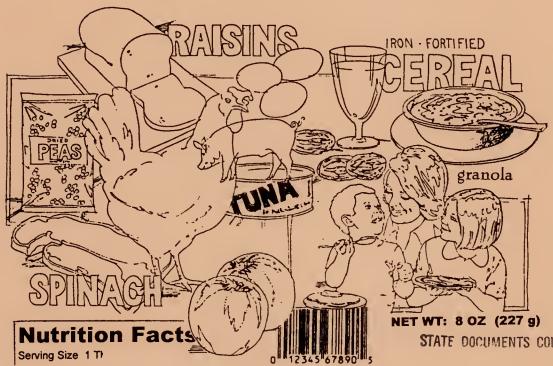
FOOD PACKAGE
LABELING GUIDE

FOR USE BY FOOD PROCESSORS AND FOOD MANUFACTURERS



Montana Department of Public Health and Human Services
MONTANA FOOD, DRUG AND COSMETIC PROGRAM
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July 2000

The purpose of this guide book is to provide assistance to food processors, manufacturers, re-packers and others in Montana with information regarding the various labeling requirements of the State and Federal regulations.

The "new" (1994) Nutrition Facts labeling requirements are only briefly discussed in this booklet. Many Montana processors or manufacturers inquire about the exemptions to the Nutrition Labeling Education Act (NLEA), and for that reason we have provided additional information pp 24 through 28 on the exemptions, and how to begin NLEA labeling on your products. If you make a nutritional claim for your product, you do not qualify for exemption. There are two other important guide booklets available. For those commercial processors who choose to do Nutrition Facts labeling you can request:

Revising Labels for Nutritional Labeling - Q & A, Volume I

Restaurants are not normally required to do Nutrition Facts labeling, unless they offer meals with nutritional claims (Low Cholesterol, Low Sodium . . .) on their menus. For those who make nutritional claims on restaurant menus or on placards at the market, you can request:

Nutrition Labeling Guide for Restaurants & Retail Stores - Q & A, Volume II

The Food/Drug & Cosmetics Program staff reviews labels for all products processed here as a courtesy to Montana entrepreneurs, and to help avoid costly reprinting and re-labeling problems, and to avoid complaints. In order to review a label, certain information regarding the product and ingredients is needed, and for that purpose an information sheet known as *Manufacturing & Labeling Checklist* is available--a copy is found in Appendix B of this booklet. You may photocopy it as you need to. Most local health departments require that new products and labels be reviewed before the facility is approved for licensing. If the product is higher risk, you may need to submit a *"Montana Process Schedule"*, also in Appendix B. If you need or want product formulations and/or labels reviewed and approved, please submit a completed *checklist* or *process schedule* along with a printers proof or photocopy of the label being proposed to the address given below. Questions regarding any aspect of processing or labeling are welcome. You can e-mail us at

sstrom@state.mt.us

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We wish you good luck in your processing enterprise.

Answers

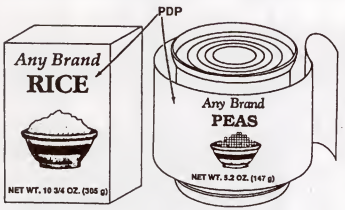
1. Where should label statements be placed on containers and packages?

There are two ways to label packages and containers:

a. Place all required label statements on the front label panel (the principal display panel or PDP), or,

b. Place certain *specified* label statements on the principal display panel, and other labeling on the information panel (the label panel immediately to the right of the principal display panel, as seen by the consumer facing the product).

2. What are the "principal display panel" and the "alternate principal display panel"?



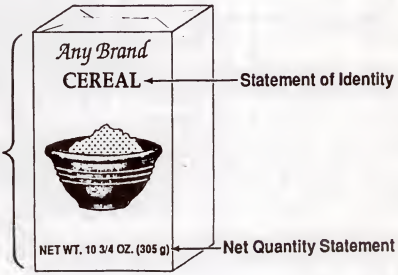
The principal display panel, or PDP, is that portion of the package label that is most likely to be seen by the consumer at the time of purchase. Many containers are designed with two or more different surfaces that are suitable for display as the PDP. These are alternate principal display panels.

21 CFR 101.1

3. What label statements must appear on the principal display panel?

Place the statement of identity, or name of the food, and the net quantity statement, or amount of product, on the PDP and on the alternate PDP. The required type size and prominence are discussed in Chapters 2 and 3.

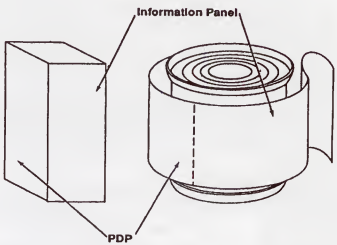
21 CFR 101.3(a) and 101.105(a)

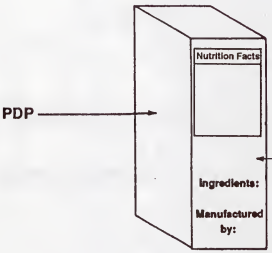


4. Which label panel is the information panel?

The information panel is the label panel immediately to the right of the PDP, as displayed to the consumer. If this panel is not usable, due to package design and construction, (i.e., folded flaps), then the information panel is the next label panel immediately to the right.

21 CFR 101.2(a)





5. What is "information panel labeling"?

The phrase "information panel labeling" refers to the label statements that are generally required to be placed together, without any intervening material, on the information panel, if such labeling does not appear on the PDP. These label statements include the name and address of the manufacturer, packer or distributor, the ingredient list, and nutrition labeling.

21 CFR 101.2(b) and (d)

6. What type size, prominence and clarity is required?

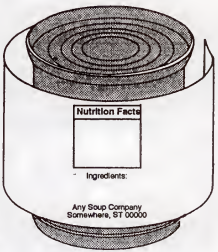
For information panel labeling, use a print or type size that is prominent, conspicuous and easy to read. Use letters that are at least one-sixteenth (1/16) inch in height based on the lower case letter "o". The letters must not be more than three times as high as they are wide, and the lettering must contrast sufficiently with the background so as to be easy to read. Do not crowd required labeling with artwork or non-required labeling.

Smaller type sizes may be used for information panel labeling on very small food packages as discussed in 21 CFR 101.2(c).

Different type sizes are specified for the nutrition facts label.

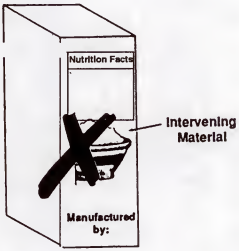
The type size requirements for the statement of identity and the net quantity statement are discussed in Chapters 2 and 3 of this booklet.

21 CFR 101.2(c) and 101.9(d)(1)(iii)



7. What is the prohibition against intervening material?

Nonessential, intervening material is not permitted to be placed between the required labeling on the information panel (e.g., the UPC bar code is not required labeling).



21 CFR 101.2(e)

8. What name and address must be listed on the label?

Food labels must list:

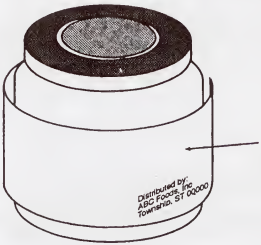
a. Name and address of the manufacturer, packer or distributor. Unless the name given is the actual manufacturer, it must be accompanied by a qualifying phrase which states the firm's relation to the product, e.g., "manufactured for" or "distributed by."

b. Street address if the firm name and address are not listed in a current city directory or telephone book;

c. City or town;

d. State (or country, if outside the United States); and

e. ZIP code (or mailing code used in countries other than the United States).



21 CFR 101.5

Name of Food

Questions

1. *What is the **name of the food statement** called and where must it be placed?*
2. *Should the **statement of identity** stand out?*
3. *What **name** should be used as the **statement of identity**?*
4. *What **placement** should be used?*
5. *When are **fanciful names** permitted as the **statement of identity**?*
6. *Is it necessary to use the **common or usual name** instead of a **new name**?*
7. *Should modified **statements of identity** be used for **sliced and unsliced** versions of a food?*
8. *What must be labeled as an **"imitation"**?*
9. *What **type size** and **degree of prominence** is required for the word "imitation" in the product name?*
10. *What causes a **juice beverage** to be required to have a **% juice declaration**?*
11. ***Where** and **how** is **% juice declared**?*
12. *Are there any **exceptions** from the **% juice requirement**?*
13. *How is the **% juice calculated**?*
14. *Should my product be **labeled** as a **"drink"** or a **"beverage"**?*
15. *Is it necessary to use the term **"concentrate"** on the label?*
16. *What **name** is used on a **mixed fruit or vegetable juice beverage**?*
17. *What **type sizes** must be used for **% juice information**?*

Answers

1. What is the "name of the food statement" called and where must it be placed?

The statement of identity is the name of the food. It must appear on the front label, or principal display panel as well as any alternate principal display panel.

21 CFR 101.3

2. Should the statement of identity stand out?

Use prominent print or type for the statement of identity. It shall be in bold type. The type size must be reasonably related to the most prominent printed matter on the front panel and should be one of the most important features on the principal display panel. Generally, this is considered to be at least 1/2 the size of the largest print on the label.

21 CFR 101.3(d)

3. What name should be used as the statement of identity?

The common or usual name of the food, if the food has one, should be used as the statement of identity. If there is none, then an appropriate descriptive name, that is not misleading, should be used.

21 CFR 101.3(b)

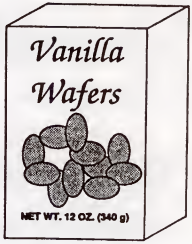
4. How should the statement of identity be placed on the label?

Place the statement of identity in lines generally parallel to the base of the package.

21 CFR 101.3(d)

5. When are fanciful names permitted as the statement of identity?

When the nature of the food is obvious, a fanciful name commonly used and understood by the public may be used.



21 CFR 101.3(b)(3)

6. Is it necessary to use the common or usual name instead of a new name ?

The common or usual name must be used for a food if it has one. It would be considered misleading to label a food that has an established name with a new name. If the food is subject to a standard of identity it must bear the name specified in the standard.

21 CFR 101.3(b) (2)

7. Should modified statements of identity be used for sliced and unsliced versions of a food?

Labels must describe the form of the food in the package if the food is sold in different optional forms such as sliced and unsliced, whole or halves, etc.

21 CFR 101.3(c)

8. What food must be labeled as an "imitation"?

A new food that resembles a traditional food and is a substitute for the traditional food must be labeled as an imitation if the new food contains less protein or a lesser amount of any essential vitamin or mineral.

21 CFR 101.3(e)

9. What type size and degree of prominence is required for the word "imitation" in the product name?

Use the same type size and prominence for the word "imitation" as is used for the name of the product imitated.

21 CFR 101.3(e)

10. What causes a juice beverage label to be required to have a % juice declaration?

Beverages that purport to contain juice (fruit or vegetable juice) must declare the % of juice. Included are beverages that purport to contain juice by way of label statements, by pictures of fruits or vegetables on the label, or by taste and appearance causing the consumer to expect juice in the beverage.

This includes non-carbonated and carbonated beverages (except soft drinks), full-strength (100%) juices, concentrated juices, diluted juices, and beverages that purpoort to contain juice but contain no juice.

21 CFR 101.30(a)

11. Where and how is % juice declared?

The % juice must be on the information panel, near the top. Only the brand name, product name, logo, or universal product code may be placed above it.

Use easily legible boldface print or type that distinctly contrasts with the other printed or graphic materlal. The type size for the % juice declaration must be not less than the largest type on the information panel, except that used for the brand name, product name, logo, universal product code, or the title phrase "Nutrition Facts."

The percentage juice declaration may be either "contains ____% juice" or "____% juice." The name of the fruit or vegetable may also be included (e.g., "100% Apple Juice").

21 CFR 101.30(e)

12. Are there any exceptions from the % juice requirement?

An exception is that beverages containing minor amounts of juice for flavoring are not required to bear a % juice declaration provided that:

(a) The product is described using the term "flavor" or "flavored,"
(b) The term "juice" is not used other than in the ingredient list, and
(c) The beverages do not otherwise give the impression they contain juice.

21 CFR 101.30(c)

13. How is % juice calculated?

Juice expressed directly from fruit or vegetables:
Compute on a volume/volume basis.

Juice made by adding water to concentrate:
Calculate using values from the Brix table in 21 CFR 101.30(h)(1) as the basis for 100% juice.

21 CFR 101.30(j), 101.30(h)

14. Should my product be labeled as a "drink" or a "beverage"?

Beverages that are 100% juice may be called "juice." However, beverages that are diluted to less than 100% juice must have the word "juice" qualified with a term such as "beverage," "drink," or "cocktail." Alternatively, the product may be labeled with a name using the form "diluted ____ juice," (e.g. "diluted apple juice").

21 CFR 102.33(g)

15. Is it necessary to use the term "concentrate" on the label?

Juices made from concentrate must be labeled with terms such as "from concentrate," or "reconsitituted" as part of the name wherever it appears on the label. An exception is that, in the ingredient statement, the juice is declared as "concentrated ____ juice and water" or "water and concentrated ____ juice," as appropriate.

21 CFR 102.33(g)

16. What name is used on a mixed fruit or vegetable juice beverage?

When stated, names of juices (except in the ingredient list) must be in descending order of predominance by volume, unless the label indicates that the named juice is used as a flavor. Examples:

"Apple, Pear and Raspberry Juice Drink"
"Raspberry flavored Apple and Pear Juice Drink"

If the label represents one or more but not all the juices (except in the ingredient list), then the name must indicate that more juices are present. Examples:

"Apple Juice Blend" "Apple Juice in a Blend of Two Other Fruit Juices"

When one or more, but not all, juices are named and the named juice is not the predominant juice, the name of the beverage must either state that the beverage is flavored with the named juice or declare the amount of the named juice in a 5% range. Examples:

(For a "raspcranberry" beverage that is primarily white grape juice with raspberry and cranberry juices added)

"Raspcranberry
Raspberry and Cranberry
flavored Juice Drink"

"Raspcranberry
Cranberry and Raspberry Juice Beverage
10-15% Cranberry Juice and
3-8% Raspberry Juice"

21 CFR 102.33(b), 102.33 (c), 102.33 (d)

17. What type sizes must be used for percentage juice information?

Product Name

The term "from concentrate" or "reconstituted" must be no smaller than one-half the height of the letters in the name of the juice.

The 5% range information generally should be not less than one-half the height of the largest type appearing in the common or usual name (may not be less than 1/16th inch in height on packages with 5 sq. in. or less area on the principal display panel, and not less than 1/8 inch in height on packages with a principal display panel greater than 5 sq. in.

Information Panel

Use easily legible boldface print or type that distinctly contrasts with the other printed or graphic material on the information panel. The type-size for the %-juice label must be not less than the largest type found on the information panel except that used for the brand name, product name, logo, universal product code, or the title phrase "Nutrition Facts."

21 CFR 101.30(e)(2), 102.5(b)(2), 102.33(d), 102.33(g)

Net Quantity of Contents Statements

Questions

*1. What is the **net quantity of contents**?*

*2. Where is the **net quantity of contents statement placed** on the label?*

*3. Should the **net quantity of contents** be stated in both **grams** and **ounces**?*

*4. Why is it necessary to calculate the **area** of the **principal display panel**?*

*5. What is the **minimum type size**?*

*6. What are the **conspicuousness** and **prominence** requirements for **net quantity statements**?*

*7. What is **included** in the **net quantity statement**?*

*8. Is **water** or **other packing medium** included in **determining the net quantity of contents** in a food container?*

*9. What is the **net quantity** of a **pressurized can**?*

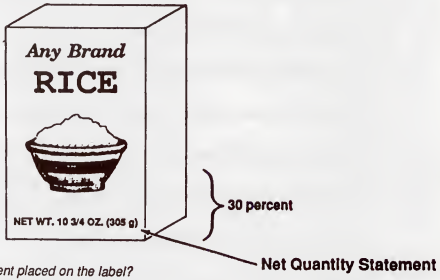
*10. What is the policy on using **qualifying phrases** in **net quantity statements**?*

Answers

1. What is the net quantity of contents?

The net quantity of contents (net quantity statement) is the statement on the label which provides the amount of food in the container or package.

21 CFR 101.105(a)



2. Where is the net quantity statement placed on the label?

The net quantity statement (net quantity of contents) is placed as a distinct item in the bottom 30 percent of the principal display panel, in lines generally parallel with the base of the container.

21 CFR 101.105(f)

3. Should the net quantity of contents be stated in both grams and ounces?

Food labels printed must show the net contents in both metric (grams, kilograms, milliliters, liters) and U.S. Customary System (ounces, pounds, fluid ounces) terms.

The metric statement may be placed either before or after the U. S. Customary statement, or above or below it. Each of the following examples is correct (additional examples appear in the regulations):

Net wt 1 lb 8 oz (680g)	500 ml (1 pt 0.9 fl oz)
Net wt 1 lb 8 oz 680g	Net contents 1 gal 3.79 L

P.L. 102-329, August 3, 1992; 21 CFR 101.105

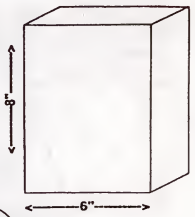
4. Why is it necessary to calculate the area of the principal display panel?

The area of the principal display panel (calculated in square inches or square centimeters) determines the minimum type size that is permitted for the net quantity statement (see next question).

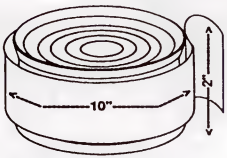
Calculate the area of the principal display panel as follows. The area of a rectangular or square principal display panel on a carton is the height multiplied by the width (both in inches or both in centimeters).

6" x 8" = 48"

Area of PDP = 48 sq. in.



To calculate the area of the principal display panel for a cylindrical container, multiply 40% of the height by the circumference.



10" x 2" = 20"

20" x 40% = 8"

Area of PDP = 8 sq. in.

5. What is the minimum type size?

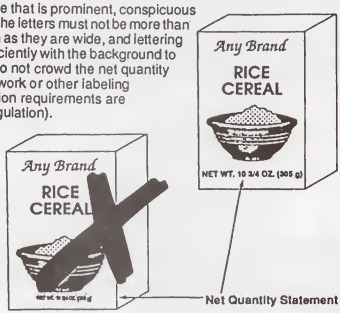
For the net quantity statements, the minimum type size is the smallest type size that is permitted based on the space available for labeling on the principal display panel. Determine the height of the type by measuring the height of the lower case letter "o" or its equivalent when mixed upper and lower case letters are used, or the height of the upper case letters when only upper case letters are used.

Minimum Type Size	Area of Principal Display Panel
1/16 in. (1.6 mm)	5 sq. in. (32 sq. cm.) or less
1/8 in. (3.2 mm)	More than 5 sq. in.(32 sq. cm.) but not more than 25 sq. in.(161 sq. cm.)
3/16 in. (4.8 mm)	More than 25 sq. in.(161 sq. cm.) but not more than 100 sq. in.(645 sq. cm.)
1/4 in. (6.4 mm)	More than 100 sq. in.(645 sq. cm.) but not more than 400 sq. in.(2580 sq. cm.)
1/2 in. (12.7 mm)	Over 400 sq. in.(2580 sq. cm.)

21 CFR 101.105(h) and (i)

6. What are the conspicuousness and prominence requirements for net quantity statements?

Choose a print style that is prominent, conspicuous and easy to read. The letters must not be more than three times as high as they are wide, and lettering must contrast sufficiently with the background to be easy to read. Do not crowd the net quantity statement with artwork or other labeling (minimum separation requirements are specified in the regulation).



21 CFR 101.105 and 101.15

7. What is included in the net quantity of contents statement?

Only the quantity of food in the container or package is stated in the net quantity statement. Do not include the weight of the container, or wrappers and packing materials. To determine the net weight, subtract the average weight of the empty container, lid and any wrappers and packing materials from the average weight of the container when filled with food.

Filled container weighs	18 oz.
Empty " "	2 oz.
Wrapper weighs	1 oz.
Net Weight	15 oz. (425 g)

21 CFR 101.105(g)

8. Is water or other packing medium included in determining the net quantity of contents in a food container?

The water or other liquid added to food in a container is usually included in the net quantity declared on a label. In some cases where the packing medium is normally discarded, the drained weight is given, e.g., olives and mushrooms.

Beans weigh	9 oz.
Water weighs	4 oz.
Sugar weighs	1 oz.
Net Weight	14 oz. (396 g)

21 CFR 101.105(a)

9. What is the net quantity of contents for a pressurized can?

The net quantity is the weight or volume of the product that will be delivered from the pressurized container together with the weight or volume of the propellant.

Whipped cream	**11.95 oz.**
Propellant	**.05 oz.**
Net Weight	**12 oz. (340 g)**

21 CFR 101.105(g)

10. What is the policy on using qualifying phrases in net quantity of contents statements?

Do not use qualifying phrases or terms that exaggerate the amount of food.

INCORRECT

Net Wt. = 2 Large oz. (5 g)

Net Wt. = 2 oz. (5 g)

CORRECT

21 CFR 101.105(o)

Ingredient List

Questions

1. *What is the* **ingredient list**?

2. *What is meant by the requirement to list ingredients in* **descending order of predominance**?

3. *Where is the* **ingredient list placed** *on the label?*

4. *What* **type size** *is required for* **ingredient lists**?

5. *Should* **water be** *listed as an* **ingredient**?

6. *Should the* **common or usual name** *always be used for* **ingredients**?

7. *Is it necessary to declare* **trace ingredients**?

8. *What foods may list* **alternative fat and oil ingredients**?

9. *What* **ingredients listing** *is necessary for* **chemical preservatives**?

10. *How are* **spices, natural flavors** *or* **artificial flavors** *declared* **in ingredient lists**?

11. *What* **listing** *is used for a* **spice** *that is also a* **coloring**?

12. *What* **ingredient listing** *is used for* **vegetable powder**?

13. *What* **ingredient listing** *is used for* **artificial colors**?

Answers

1. What is the ingredient list?

The ingredient list on a food label is the listing of each ingredient in descending order of predominance.

"INGREDIENTS: Pinto Beans, Water, and Salt"

21 CFR 101.4(a)

2. What is meant by the requirement to list ingredients in descending order of predominance?

Descending order of predominance means that the ingredients are listed in order of predominance by weight, that is, the ingredient that weighs the most is listed first, and the ingredient that weighs the least is listed last (see illustration for question #3).

21 CFR 101.4(a)

3. Where is the ingredient list placed on the label?

The ingredient list is placed on the same label panel as the name and address of the manufacturer, packer or distributor. This may be either the information panel or the principal display panel. It may be before or after the nutrition label and the name and address of the manufacturer, packer or distributor.

21 CFR 101.4(a)

4. What type size is required for ingredient lists?

Use a type size that is at least 1/16 inch in height (lower case "o") and that is prominent, conspicuous, and easy to read. See the type size, prominence, and clarity requirements for information panel labeling discussed in the first chapter of this booklet.

21 CFR 101.2(c)

5. Should water be listed as an ingredient?

Water added in making a food is considered to be an ingredient. The added water must be identified in the list of ingredients and listed in its descending order of predominance by weight.

"INGREDIENTS: Water, Navy Beans, and Salt"

21 CFR 101.4(a)

6. Should the common or usual name always be used for ingredients?

Always list the common or usual name for ingredients unless there is a regulation that provides for a different term. For instance, use the term "sugar" instead of the scientific name "sucrose".

"INGREDIENTS: Apples, Sugar, Water, and Spices"

21 CFR 101.4(a)

7. Is it necessary to declare trace ingredients?

It depends on whether the trace ingredient is present in a significant amount and has a function in the finished food. If a substance is an incidental additive and has no function or technical effect in the finished product, then it need not be declared on the label. An incidental additive is usually present because it is an ingredient of another ingredient. Sulfites are considered to be incidental only if present at less than 10 ppm.

21 CFR 101.100(a)(3)

8. What foods may list alternative fat and oil ingredients?

Listing alternative fat and oil ingredients ("and/or" labeling) is permitted only in the case of foods that contain relatively small quantities of added fat or oil ingredients (foods in which added fats or oils are not the predominant ingredient) and only if the manufacturer is unable to predict which fat or oil ingredient will be used.

"INGREDIENTS: . . . Vegetable Oil (contains one or more of the following: Corn Oil, Soybean Oil, or Safflower Oil) . . . ."

21 CFR 101.4(b)(14)

9. What ingredient listing is necessary for chemical preservatives?

When an approved chemical preservative is added to a food, the ingredient list must include both the common or usual name of the preservative and the function of the preservative by including terms, such as "preservative," "to retard spoilage," "a mold inhibitor," "to help protect flavor," or "to promote color retention."

> **"INGREDIENTS: Dried Bananas, Sugar, Salt, and Ascorbic Acid to Promote Color Retention"**

21 CFR 101.22(j)

10. How are spices, natural flavors or artificial flavors declared in ingredient lists?

These may be declared in ingredient lists by using either specific common or usual names or by using the declarations "spices," "flavor" or "natural flavor," or "artificial flavor."

> **"INGREDIENTS: Apple Slices, Water, Cane Syrup, Corn Syrup, Modified Corn Starch, Spices, Salt, Natural Flavor and Artificial Flavor"**

21 CFR 101.22(h)(1)

11. What listing is used for a spice that is also a coloring?

Spices, such as paprika, turmeric, saffron and others that are also colorings must be declared either by the term "spice and coloring" or by the actual (common or usual) names, such as "paprika."

21 CFR 101.22(a)(2)

12. What ingredient listing is used for vegetable powder?

Vegetable powders must be declared by common or usual name, such as "celery powder."

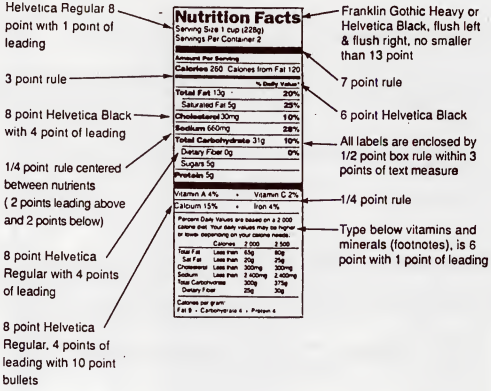
21 CFR 101.22(h)(3)

13. What ingredient listing is used for artificial colors?

It depends on whether the artificial color is a certified color:

> **Certified colors: List by specific or abbreviated name such as "FD&C Red No. 40" or "Red 40."**
>
> **Non-certified colors: List as "artificial color," "artificial coloring," or by their specific common or usual names such as "caramel coloring" and "beet juice."**

21 CFR 101.22(k)(1) and (2), 21 CFR 74.705(d)(2)



A. Overall

Nutrition Facts Label is boxed with all black or one color type printed on a white or neutral backgground.

B. Typeface and Size

1. The "Nutrition Fact" label uses 6 point or larger Helvetica Black and/or Helvetica Regular type. In order to fit some formats the typography ,may be kerned as much as -4, (tighter kerning reduces legibility).

2. Key nutrients & their % Daily Value are set in 8 point Helvetica Black (but "%" is set in Helvetica Regular).

3. "Nutrition Facts" is set in either Franklin Gothic Heavy or Helvetica Black to fit the width of the label flush left and flush right.

4. "Serving Size" and "Servings per container" are set in 8 point Helvetica Regular with 1 point of leading.

5. The table labels (for example; "Amount per Serving") are set in 6 point Helvetica Black.

6. Absolute measures of nutrient content (for example; "1g") and nutrient subgroups are set in 8 point Helvetica Regular with 4 points of leading.

7. Vitamins and minerals are set in 8 point Helvetica Regular, with 4 points of leading, separated by 10 point bullets.

8. All type that appears under vitamins and minerals is set in 6 point Helvetica Regular with 1 point of leading.

C. Rules

1. A 7 point rule separates large groupings as shown in the example. A 3 point rule separates calorie information from the nutrientinformation.

2. A hairline rule or 1/4 point rule separates individual nutrients, as ahown in the example. Descenders do not touch rule. The top half of the label (nutrient information) has 2 points of leading between the type and the rules, the bottom half of the label (footnotes) has 1 point of leading between the type and the rules.

D. Box

All labels are enclosed by 1/2 point box rule within 3 points of text measure.

Answers

1. Are "Nutrition Facts" labels required on all foods?

The new nutrition label (illustrated on the preceding page) is required on most food packages labeled on or after May 8, 1994. The illustration indicates suggested typeface and style to help assure readibility and conspicuousness. Not all of these type specifications are required. The mandatory type specifications are listed in § 101.9(d). Unlike the illustrative examples in this booklet, (1) Any legible type style may be used, not just Helvetica, (2) The heading "Nutrition Facts" must be the largest type size in the nutrition label, i.e., it must be larger than 8-point, but does not need to be 13-point, and (3) There is no specific thickness required for the three bars that separate the central sections of the nutrition label.

21 CFR 101.9(a) and 101.9(a)(1)

Below are listed categories providing exemptions or special provisions for nutrition labeling. A food package loses those exemptions, which are asterisked, if a nutrition claim is made or nutrition information is provided:

Summary of Exemption	Regulation #
*Manufactured by small businesses	21 CFR 101.9(j)(1)
*Food served in restaurants, etc. or delivered to homes ready for immediate consumption	21 CFR 101.9(j)(2)
*Delicatessen-type food, bakery products and confections that are sold directly to consumers from the location where prepared	21 CFR 101.9(j)(3)
*Foods that provide no significant nutrition such as instant coffee (plain, unsweetened) and most spices	21 CFR 101.9(j)(4)
Infant formula, and infant and junior foods to 4 years (modified label provisions for these categories)	21 CFR 101.9(j)(5) and 101.9(j)(7)
Dietary supplements of vitamins and minerals (exemption does not apply to dietary supplements in conventional food form)	21 CFR 101.9(j)(6)
Medical foods	21 CFR 101.9(j)(8)

Question 1. (continued)

Bulk foods shipped for further processing or packaging before retail sale	21 CFR 101.9(j)(9)
*Fresh produce department and seafood department in grocery stores (a voluntary nutrition labeling program using placards covers these foods)	21 CFR 101.9(j)(10) and 101.45
Single-ingredient fish or game meat may be labeled on basis of 3-ounce cooked portion (as prepared). Custom-processed fish and game are exempt from nutrition labeling.	21 CFR 101.9(j)(12)
Certain egg cartons (nutrition information inside lid or on insert in carton)	21 CFR 101.9(j)(14)
Packages labeled "This unit not labeled for retail sale" within multiunit package, and outer wrapper bears all required label statements	21 CFR 101.9(j)(15)
Self-service bulk foods—nutrition labeling by placard, or on original container displayed clearly in view	21 CFR 101.9(a)(2) and 101.9(j)(16)
Donated food that is given free (not sold) to the consumer	You are not required to put "Nutrition Facts" labels on donated food unless the donated food is later placed on sale (the law applies only to food that is "offered for sale") – 21 CFR 101.9(a)

July 1, 2000

TO: **Montana Food Processors**

FROM: **S. C. Strom**
Montana Food, Drug & Cosmetic Program

Subject: **NUTRITION FACTS --- Small Business Exemption**
Restaurant Exemption --- Low Volume Exemption

According to federal (FDA) regulations, NUTRITION FACTS labeling is required for all processed and packaged food, except those mentioned on pages 22 & 23. The first exemption is referred to as a "small business exemption". This memo is intended to assist you in determining if you qualify for that exemption or one of the several other exemptions shown.

SMALL BUSINESS EXEMPTION *{21 CFR 101.9(j)(1)}* (See also: SMALLER THAN SMALL on the next page)

If your operation is strictly confined to onsite sales, (e.g. a retailer or processor who sells only direct to the consumer) your packaged products are exempt if they are not offered for sale at any other location and if your food sales are less than $50,000 per year or total sales (both food and non-food sales) are less that $500,000 per year. For example, if you manufacture chokecherry syrup for sales at your store, and also sell souvenirs, and your total sales are $600,000 ($20,000 in chokecherry syrup and $580,000 in souvenirs) you can claim the small business exemption since your food sales are under $50,000. Another example, is a case where you process and sell only foods - several types of jam, jelly, syrup, soup mix, and bisquit mix. Lets say that collectively, your sales are $350,000-all food. Because you are under the $500,000 ceiling, you may file the exemption. Of course, if your food sales were above $500,000 - you could not claim this exemption for your products.

LOW-VOLUME FOODS *{21 CFR 101.9(j)(18)(iii)}*

For all other products, including those produced and sold wholesale, i.e., to warehouses or other retailers, or sold both wholesale and retail, exemption may be claimed if the volume of the product manufactured and sold is low (< 100,000 units), and if the processor is a small business (< 100 FTE's). In order to qualify for this exemption, a food product must meet all of the following criteria:

1) The processor claiming the exemption must have a total of fewer than 100 full time equivalent employees (FTE's), and;

2) during the previous 12 months, fewer than 100,000 units (packages) of the product were sold or distributed, and;

3) the product labeling must make no nutritional claims, nor provide any nutritional information (such as "low sodium"), and;

4) the notice must be in writing, submitted prior to the beginning of the period for which it is to apply.

If your firm has a product or products for which you intend to claim the small business exemption, or the low volume exemption, remember that it must be in writing (Appendix A is a small supply of

forms), and it must be filed every year. Photocopy the form as necessary.

There are instructions on the back of the forms for your use. We suggest that you send the form by certified mail (FDA will not respond, just to say they received it) and keep a copy of the form in your business files. FDA will put your firm and product on a list of exemptions that it maintains. You may want to photocopy the blank form for future use. Note that the exemptions are for products, not the company or producer. Thus, it may be necessary to file more than one exemption notice, while some products by the same producer, may be required to have NLEA labeling. Also, do not send it to us, it should be sent to FDA at the address on the back of the form.

SMALLER THAN SMALL - FILING NOT REQUIRED *{21 CFR 101.9 (18)[iv]}*

For the very smallest of processors, who have fewer than the equivalent of 10 FTE's, and which produce a product which sells fewer than 10,000 units per year, it is not even necessary to file the exemption form for the following year, provided, no nutritional claims or content claims are made on the label or in the labeling information. (The number of FTE's would include part time employees.) "Units" in this case means the total number of containers of a given food with the same identity, same process even though all sizes may be included. For example, a producer of huckleberry jam in 6 oz and 10 oz jars would include all jars of both sizes in order to determine if the number of units was under 10,000.

THE RESTAURANT EXEMPTION

In Montana, the majority of food purveyors qualify for an exemption in one of 2 categories: as a small business, as described above, as a food service or ready-to-eat food seller (e.g. restaurant, coffee shop, in-store bakery, in-store food or salad bars, drive-through fast-food etc.). This exemption is automatic, you do not have to file, provided no nutritional or health claims are made on the menu or other advertising, and provided that you do not produce food items to be sold elsewhere (wholesale).

If a restaurant has special low-calorie or health oriented meals on the menu or if it chooses to provide nutritional labeling, information can be obtained from the Montana Food and Drug Program office in Helena at (406) 444-5306, or e-mail requests to *sstrom@state.mt.us*. A booklet is available dealing with **"Nutritional Labeling for Restaurants and Retail Establishments"**. This booklet is much easier to understand than the actual regulations.

WHERE TO GET COPIES

If you need an actual copy of a provision of any of the nutritional labeling or exemption regulations, please contact our office. We can provide photocopies of specific sections, but copying an entire *Part* or *Sub-part* of the regulation can usually be avoided. The regulation is found in bound volumes, and each part is often lengthy and difficult to read. A complete 3 volume set of the food regulations is available from the address shown below for about $75. This would include the standards for manufacturing, thermal processing, sanitation, bottled water, rodent control, dietary supplements etc., as well as labeling requirements. Telephone (202) 783-3238 for prices and ordering info.

U.S. Government Printing Office
Superintendent of Documents,
Mail Stop: SSOP
WASHINGTON DC 20402-9328

❖ ❖ ❖ ❖ ❖ ❖ ❖ ❖

UNIVERSAL PRODUCT CODE - UPC (Bar Codes)

The Uniform Code Council, Inc is a not-for-profit membership corporation which administers the Universal Product Code--sometimes called the "bar code". They are the central management and information center for both manufacturers and retailers participating in the system. Support and cooperation between manufacturers and retailers has been achieved which has allowed interstate uniformity of scanning codes for food products. Retailers have now come to depend on this 12 digit UPC for their automated checkout scanning. The first 6 digits are assignd by the UPC council; and the second 5 are assigned by the manufacturer (the 12th is a check digit).

The Uniform Code Council manages symbol specifications, UPC package locations, general standards, color guidelines and code numbering systems, etc. They are not affiliated with a government agency, and membership is voluntary. You can contact them at **1-800-543-8137** or at the following address:

Uniform Code Council, Inc
8163 OLD YANKEE ROAD SUITE J
DAYTON OH 45458

Dayton office phone: (513) 435-3870

The Montana Food & Drug Program office in Helena keeps a small supply of their brochures, which gives more detail and tells you how to get started. You can obtain one by calling (406) 444-5306.

REVISING YOUR LABELS TO PROVIDE A NUTRITION FACTS PANEL

There is an article at the end of this booklet (Appendix C) which will provide some basic information. We also have a guide booklet called **Revising Labels for Nutritional Labeling** available - (406) 444-5306. It provides gudance in easy-to-understand terminology and is in question/answer format.

LABORATORIES

Our office does not keep a listing of qualified or recommended laboratories, but you may be able to obtain guidance from the American Council of Independent Laboratories (ACIL). ACIL is a third-party scientific, testing and research firm. They have hundreds of member labs classified according to geographic location and areas of expertise. You may inquire about labs which provide nutrition labeling testing and services; they may be able to fax you a list. Many consultant/labs do both the necessary analysis, and the label graphics layout.

ACIL
1629 K Street Northwest
Washington D.C. 20006 ***(202)*** **887-5872**

We do not wish to imply that laboratory testing is mandatory; it can be a considerable expense. However, if you intend to collect the data using other means, it must still be accurate, within reason. There may be data bases of nutritional information on certain products and ingredients which are standardized and which may be available via computer, or perhaps in reference books or elsewhere. Please understand that the accuracy of such information is the responsibility of the processor. The actual nutrient content of a certain product (i.e. a tomato) may vary depending on the season, where it was grown, type of soil it was grown in, species of plant etc. These variations are usually small, but if the ingredient makes up a majority of the product, variations in finished product nutritional values are possible. Reliable sources which provide consistent quality ingredients are important, to minimize variations. You will want to have confidence in the the data on nutritional values that you will use for your particular label.

OTHER SOURCES OF INFORMATION

Other possible sources of help include the MSU Extension Service in Bozeman, (406) 994-5702. You may wish to consult with other Montana processors who have already utilized a laboratory or labeling consultant in developing the revised labels for their products to display **NUTRITION FACTS**. Their experience may be of help to you, in selecting a lab or consultant. Sometimes ingredient suppliers can provide you with information and advice.

If you intend to make up your own label layout, based on data already available, additional information and review of the layout is available at the Montana Food & Drug Program office in Helena -- (406) 444-5306. We can fax you examples, excerpts of the standards, and other guidance information. If you want to have a proof of your label reviewed for content, arrangement, letter size, ingredient information, or Nutrition Facts, you can use the **Manufacturing & Labeling Checklist** (Appendix B) of this booklet to provide the necessary background information and send a copy of your label (either a photocopy or printers proof) for review. Feel free to photocopy this document for additional products.

Not all NUTRITION FACTS label panels have to contain all components of the panel. The example (c) on the next page -- is for a product (vegetable oil) which qualifies for simplified format because it contains insignificant amounts of seven or more of the 13 nutrient categories: Calories, total fat, saturated fat, cholesterol, sodium, total carbohydrates, dietary fiber, sugars, protein, Vitamin A, Vitamin C, calcium or iron. The shortened (smaller) format size is based on the label panel being less than 40 square inches. The footnote (that part below the asterisk) is not required if the product qualifies for the simplified format. Example (b) is a soft drink which also uses the shortened size and simplified format.

Example (a) is for a product which has more that 40 square inches of label space and must therefore be full size, and which contains a variety of nutrients so that it does not qualify for simplified format.

Example [a] Full size label - full format

Nutrition Facts

Serving Size 1/2 cup (114g)
Servings Per Container 4

Amount Per Serving

Calories 260 Calories from Fat 120

	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**11%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4% • Vitamin C 2%
Calcium 15% • Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Example [b] Simplified format

Nutrition Facts

Serving Size 1 can (360 mL)

Amount Per Serving

Calories 140

	% Daily Value*
Total Fat 0g	**0%**
Sodium 20mg	**1%**
Total Carbohydrate 36g	**12%**
Sugars 36 g	
Protein 0g	

* Percent Daily Values are based on a 2,000 calorie diet.

Example [c] Simplified format - including required statement in lieu of footnote.

*Percent Daily Values are based on a 2,000 calorie diet.

Nutrition Facts

Serving Size 1 Tbsp (14g)
Servings Per Container 64

Amount Per Serving

Calories 130 Calories from Fat 130

	% Daily Value*
Total Fat 14g	**22%**
Saturated Fat 2g	**10%**
Polyunsaturated Fat 4g	
Monounsaturated Fat 8g	
Sodium 0mg	**0%**
Total Carbohydrate 0g	**0%**
Protein 0g	

Not a significant source of cholesterol, dietary fiber, sugars, vitamin A, vitamin C, calcium, and iron

* Percent Daily Values are based on a 2,000 calorie diet.

There are 5 core nutrients, (calories, total fat, sodium, total carbohydrate, and protein) which must be listed -- even on labels which are simplified or shortened format. They must be listed, even if they are present in insignificant amounts.

(Information on saturated fat included either voluntarily, or because of a nutritional claim.

REVISING YOUR LABELS TO PROVIDE A NUTRITION FACTS PANEL (Continued)

SERVING SIZE DETERMINATIONS

After establishing that the product in not exempt, or that you do not want to file for exemption, the next steps in creating a Nutrition Facts label are investigating the actual nutrient content of the product or ingredients, composing that data based on serving size. All values expressed in the NUTRITION FACTS panel must be terms of the stated "serving size", and the % daily value.

Serving sizes for various foods are based on established reference amounts as provided in the federal regulation (21 CFR 101.12(b). Appendix D contains the Reference Amounts tables for determination of serving size, exactly as they appear in the regulation. The serving size is followed by a parenthetical listing of the equivalent metric quantity. Serving size is expressed in common household measure(i.e., cup; tablespoon, teaspoon; piece, slice, fraction (e.g. ¼ pizza); ounce, fluid ounce) and followed by the equivalent metric quantity in parenthesis. The metric quantity for serving size is not required on the **NUTRITION FACTS** panel for single serving containers unless nutrition information is required on a drained weight basis.

A package that is sold individually and contains less than 200% of the applicable reference amount is considered to be one serving. When serving size is expressed on a drained weight basis, and the number of servings may vary due to natural variation in the product, the manufacturer may state the typical number of servings per container (e.g., maraschino cherries; usually 5 servings).

In calculating the "Amount Per Serving", it is likely that you may need to round off the amount. Rounding rules for this purpose are included in the last page of Appendix D. Nutrients are listed in the rounding table in the order in which they must be listed on the nutrition label. Nutrients are listed in a column and immediately followed by the quantitative amount with a "g" for grams, "mg" for milligrams and "IU" for International Units.

Greater detail and examples of composition of labels are given in the second volume of this series -- which is also available from the Montana Food & Drug Program (406) 444-5306. It is called **Food Labeling -- Revising Labels for Nutritional Labeling/ Questions and Answers , Volume I**.

If you operate a restaurant or other type of food service, and intend to do Nutritional Labeling you will want the third guidebook of the series, also available at the Montana Food & Drug Program (406) 444-5306. This guidebook is called **Food Labeling -- A Guide for Restaurants & Retail Establishments/ Questions & Answers, Volume II**.

This section on Nutrition labeling is intended to be introductory only. **Volume I** above will be needed in order to complete the label and to insure that it is laid out properly. The accuracy of the data is another issue which is dealt with in greater detail in the above described booklets. If you are manufacturing food for children or infants, please contact our office or FDA for further guidance as these are special cases with different requirements.

Appendix A

SMALL BUSINESS FOOD LABELING EXEMPTION NOTICE
FOR PRODUCT LABELING UNDER THE NLEA EXEMPTIONS
CITED IN 21 CFR 101.9 (j)

1) Name of Firm_____

2) Address of Facility _____

_____ State _____ Zip_____

3) Name of Food Product for which Exemption is being claimed: *[Use continuation sheets as necessary]*

_____ _____
_____ _____
_____ _____
_____ _____

4) Name and Address of manufacturers of the products listed in Item 3 - if different from the firm listed in item 1 and 2. *[Use continuation sheets as necessary]*

_____ _____
_____ _____
_____ _____
_____ _____

5) Average number of Full-Time Equivalent Employees _____ *[Include part time & seasonal)*
for the 12 month period preceding the exemption. May 8, _____ through May 7, _____
[✓✓✓ this year]

Exemption will be for the 12 months from May 8th, this year through May 7th, next year.

6) Approximate total number of units of each product sold in the U.S. during the 12 month period preceeding the exemption -- same dates as entered in #5 above. *[Continuation sheets are OK] .*

No. of Units	Product	No. of Units	Product

7) The undersigned certifies that the above information is a true and accurate representation of the operations of _____ *[enter name of firm].*
The undsigned will notify the Office of Food Labeling of the date on which the average number of full-time equivalent employees exceeds 100 for a 12 month period, or the number of units of any of the above food products sold in the United States exceeds 100,000 units for a 12 month period for which the exemption is being claimed herein.

Signature _____
Name & Title _____

Small Business NLEA Food Labeling Exemption Notice

Criteria and Instructions for Completion

CONTINUING EXEMPTION AVAILABLE FOR FIRMS WITH LESS THAN 100 EMPLOYEES

Exemptions from the requirements of the Nutrition Labeling Education Act (NLEA) may be claimed using this form. The exemption is available for products and firms with less than the equivalent of 100 full time employees during the 12 month period preceding the exemption. The exemption is available on a 12 month renewable basis through May 7, 2002 -- if the product and firm meet all of the following criteria.

A] The product provides no nutrition information and makes no NLEA defined claims.

B] The firm claiming the exemption has less than the equivalent of 100 full-time employees.

C] During the previous 12 months less than 100,000 units of the product were sold or it is anticipated that less than 100,000 will be sold during the period for which an exemption is claimed. (This includes all units of a product in all container sizes of the same identity)

D] The exemption must be claimed prior to the period for which it is to apply. The exemption periods run from May 8th of the year through May 7th of the following year.

NOTE: 21 CFR 101.9 [j] [18](iv) indicates that the exemption notice must be filed...**except that if the person (firm) is not an importer, and has fewer than 10 full-time equivalent employees, that person (firm) does not have to file an exemption notice for any food product with annual sales of fewer than 10,000 total units.**

EXEMPTION NOTICE - INSTRUCTIONS FOR COMPLETION

Send completed forms to: USFDA / Office of Food Labeling (HFS-150), Center for Food Safety & Applied Nutrition, 200 C Street SW, Washington DC 20204

1. Name of Firm: *Enter the recognized legal name of the firm which is processing and labeling the product.*

2 Address of Facility: *Enter the mailing address for the principal place of business of the firm.*

3 Name of Food Product for which Exemption is being claimed: *The food product name should include the trade name and the common name. Continuation sheets may be attached.*

4. Name and address of Manufacturer: *If the name of the manufacturer is different from the firm name given above in #1, provide the* ***name(s)*** *and* ***address(es)*** *of the manufacturers of the food products for which exemption is being claimed.*

5. Average number of Full-Time Equivalent Employees: *Enter the approximate average number of persons employed by the firm for the year preceding the year for which an exemption is claimed. The average number should include all persons employed by the firm and it's affiliates. It can be calculated using the following formula: Total number of employee/hours paid divided by 2080 hours a year = Average number of FTE's. Employee/hours should include overtime hours, seasonal employee hours, and part-time hours. The FTE calculations are for the year preceeding the exemption year--enter the "year" numbers for that 12 month period.*

6. Approximate total number of units sold in the U.S. during the 12 month period preceeding the exemption: *If it is May or after, the actual number of units sold for each product in the preceeding 12 months is probably available. If it is early in the year, prior to May, an estimate may be necessary. The "number of units" sold is defined is the sum of all units of all package sizes of the food product, in the form in which it is sold to consumers. A "food product" is regarded as a food in any sized package produced by a single manufacturer, or which bears the same brand name; which bears the same statement of identity; and which has similar preparation methods.*

7. Certification *This form is to be signed by a responsible individual for the firm who can certify to the authenticity of the information presented on the form. The person signing will commit to notifying the Office of Food Labeling when the numbers of employees or number of unit sold in the U.S. exceed the applicable numbers for an exemption.*

Reviewed by _____

Date received _____

MANUFACTURING & LABELING CHECKLIST

RETURN TO: MONTANA FOOD, DRUG & COSMETIC PROGRAM
COGSWELL BLDG
PO BOX 202951
HELENA MT 59620-2951 Phone (406) 444-5306

The following questions should be answered about your product. If the question does not apply to your particular product write "N/A" and if not obvious, then tell why it does not apply. If you have questions about the meaning of some questions please feel free to call us at the above number.

----- INCOMPLETE APPLICATIONS MAY BE RETURNED -----

NAME OF MANUFACTURING/PROCESSING ESTABLISHMENT

_____

_____

NAME OF OWNER CORPORATION

_____

CONTACT PERSON _____

STREET ADDRESS OF POINT OF MANUFACTURE

_____

_____

MAILING ADDRESS (if different) _____

CITY _____ STATE _____ ZIP _____

TELEPHONE # (_____) - _____ FAX # (_____) - _____

IS THIS PRODUCT INTENDED TO BE A:

FOOD _____ FOOD SUPPLEMENT _____

COSMETIC _____ DRUG/MEDICATION _____

COMMON NAME FOR THE PROPOSED PRODUCT _____
(i.e. - "Pancake mix")

YOUR TRADE NAME FOR THE PRODUCT _____
(i.e. - "Blue Mountain Buckwheat Pancake Mix")

IS THE PROCESSING CONFINED TO REPACKING? _____ YES _____ NO

EXPLAIN _____

WILL THERE BE ONSITE RETAIL SALES? _____ YES _____ NO

WILL THE PRODUCT BE SOLD WHOLESALE *(case lots)* FOR RE-SALE ELSEWHERE? _____ YES _____ NO

LIST ALL INGREDIENTS IN DESCENDING ORDER OF PREDOMINANCE BY WEIGHT, AND THE WEIGHTS AND MEASURE OF EACH PER BATCH, IDENTIFYING BATCH SIZE.

BATCH SIZE _____ BATCH WEIGHT _____

INGREDIENT	MEASURE PER BATCH	WEIGHT PER BATCH

LIST ALL INGREDIENTS WITHIN INGREDIENTS IN PARENTHESIS
Mayonnaise (egg yolks, vegetable oil, lemon juice, salt, vinegar, oxystearin...)

_____

_____

_____

_____

(A copy of page 2 is needed for each variation, including label exhibit. For example--one set for blueberry muffins, and another set for poppyseed muffins, and another for brownies, etc. Photocopy p. 2 as needed.)

ARE ANY RESTRICTED INGREDIENTS TO BE USED OR ALREADY IN YOUR PRODUCT *(Sulfites, sweeteners, flavorings)*? YES _____ NO _____

LIST HERE _____

_____

_____

LIST ALL FOOD COLORINGS, WHETHER ADDED DIRECTLY OR CONTAINED WITHIN INGREDIENTS USED IN THE PRODUCT *(ingredients within ingredients)*.

_____

_____

ARE ANY ORGANIC CLAIMS BEING MADE? YES _____ NO _____ IF YES, THEN ATTACH DOCUMENTATION.

ARE ANY OTHER CLAIMS BEING MADE SUCH AS "PURE", "NATURAL" "LIGHT", "LOW CHOLESTEROL", "LOW FAT", "REDUCED SALT", ETC? YES _____ NO _____ IF YES, THEN ATTACH DOCUMENTATION.

IS NUTRITIONAL LABELING INFORMATION BEING INCLUDED? YES _____ NO _____ IF YES, THEN ATTACH DOCUMENTATION, OR EXPLANATION.

NOTE: Nutrition labels required after May 1994, with some exceptions - including small business producing less than 10,000 units last year and having fewer than 50 employees, if no label claims are made or implied. For further description of NLEA exemption see pp. 22-28 of the LABELING GUIDE, or call us at the number given above.)

WILL THE PRODUCT LABEL REQUIRE REFRIGERATION? YES _____ NO _____

MANUFACTURED FOOD SECTION

LOW ACID CANNED FOODS 1) Have pH greater than 4.6 and water activity greater than 0.85, 2) are sealed hermetic *(air-tight)* container, 3) receives a heat treatment for the purpose of achieving commercial sterility, 4) and is normally stored under non-refrigerated conditions.

AN ACIDIFIED FOOD is a low acid food to which acid(s) or acid food(s) are added. It has a water activity greater than 0.85 and a finished equilibrium pH of 4.6 or below. An acidified food is normally stored and distributed under non-refrigerated conditions. *(Carbonated soft drinks are not acidified foods.)*

IF YOU MEET EITHER OF THE ABOVE CRITERIA YOU MUST HAVE A SCHEDULED PROCESS, APPROPRIATE TRAINING , AND YOU MUST REGISTER YOUR PRODUCT WITH THE FDA *(FOOD & DRUG ADMINISTRATION)*. IF APPLICABLE ARE YOU REGISTERED WITH FDA?

N.A. _____ YES _____ NO _____

IF ACIDIFIED FOODS OR LOW-ACID FOODS ARE TO BE PRODUCED & PACKAGED, INCLUDING SALSA, DRESSINGS, SAUCES ETC. ATTACH LAB TEST RESULTS FOR pH.

DESCRIBE IN DETAIL YOUR MANUFACTURING PROCESS: INCLUDE TIMES, TEMPERATURES OF COOKING PROCESS IF APPLICABLE, SOURCE OF PRINCIPAL INGREDIENTS & ALSO DESCRIBE SET UP PROCEDURES, FINISHED PRODUCT HANDLING, CLOSURES, PRODUCTION CODES OR DATE CODES, SHELF LIFE, QUALITY CONTROL OR TESTING PROCEDURES ETC. *(Use additional sheets if necessary)*

PACKAGING MATERIAL, CONTAINER CLOSURES: *(describe)*

HOW WILL IT BE SOLD? _____
(retail stores, mail orders, case lots for wholesale, onsite retail, Internet.....)

INTERSTATE? _____

LABELS - MOST COUNTIES REQUIRE LABELING REVIEW & APPROVAL PRIOR TO LICENSING. AN ACTUAL SIZE LABEL EXHIBIT IS NEEDED FOR THIS PURPOSE. A CLEAR PHOTOCOPY WILL DO.

ATTACH PRINTERS PROOF OR PHOTOCOPY OF PROPOSED LABEL HERE ⇩, OR ON A SEPARATE SHEET. ⇨

IF THIS IS A NEW FACILITY, HAVE YOU CONTACTED THE LOCAL HEALTH DEPARTMENT FOR APPROVAL AND INSPECTION OF YOUR FACILITY? YES _____ NO _____

NAME OF THAT DEPARTMENT _____

WHO DID YOU TALK TO THERE _____

DID YOU HAVE A CURRENT *"Food Purveyor License"* ISSUED BY THE DEPARTMENT OF PUBLIC HEALTH & HUMAN SERVICES *(FOOD & CONSUMER SAFETY)*? YES _____ NO _____

IF YES, GIVE NAME ISSUED UNDER: _____

AND THE NUMBER OF THE LICENSE: F_____

AND THE ENDORSEMENT TYPE (F1, F2, F6, ETC): _____

AND THE COUNTY IN WHICH LICENSE WAS ISSUED: _____

AND THE PRODUCT CODES APPROVED (IF ANY): _____

WATER BOTTLERS

IF YOUR PRODUCT IS WATER, HAVE YOU CONTACTED THE *DRINKING WATER PERMIT SECTION* OF THE **MONTANA DEPARTMENT OF ENVIRONMENTAL QUALITY** *(DEQ)*?

YES _____ NO _____ N/A _____

DATE _____ CONTACT PERSON _____

HAVE PLANS BEEN SUBMITTED TO THAT AGENCY AND APPROVED?

YES _____ NO _____ PWS NUMBER ISSUED _____

PRIOR APPROVAL AND A PWS NUMBER ARE REQUIRED PRIOR TO LICENSING. PRODUCTION CODING/DATE CODING ARE REQUIRED FOR BOTTLED WATER.

'NUTRITION FACTS'

To Help Consumers Eat Smart

by Paula Kurtzweil

Susan Thom, of Parma, Ohio, knows how important it is for people to know the number of calories from fat they eat each day.

As a registered dietitian, she counsels patients on the need to limit fat consumption to 30 percent or less of total daily calories. As a person with diabetes, and thus at increased risk for heart disease, she strives to do the same for herself.

But, in the past, obtaining that information from the food label has required some mathematical skill—namely, multiplying the total grams (g) of fat in a serving by 9, since 1 g of fat contains 9 calories.

"It does take time," Thom said. "But if you want to feed yourself well, you have to look at the label."

Help is on the way. For Thom and millions of other Americans who seek to restrict their fat intake to recommended levels, a new dietary component is being added to the food label—"calories from fat."

It's just one of many new items of diet-related information manufacturers are required to offer on their food products by 1994. There also will be information on saturated fat, cholesterol, dietary fiber, and other nutrients that relate to today's health concerns, such as heart disease, cancer, and other diseases linked, at least in part, to diet.

There will be more complete nutrient content information because almost all the required nutrients will have to be listed as a percent of the Daily Value. There will be more uniform serving sizes, too, which will make nutritional comparisons between foods easier. And, because nutrition labeling is now mandatory for almost all processed foods, there will be a lot more products with this important information.

"The new information is going to be very helpful for consumers," said Virginia Wilkening, a registered dietitian in FDA's Office of Food Labeling.

"Some of the nutrients—saturated fat and cholesterol—have been allowed on the label before but on a voluntary basis," she said. "Dietary fiber and sugars were not allowed in the nutrition label. With the new label, consumers will soon have information about these and other nutrients, which can help them choose their foods more wisely."

The new requirements for nutrition labeling are spelled out in regulations issued in January 1993 by FDA and the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS). FDA's regulations meet the provisions of the Nutrition Labeling and Education Act of 1990 (NLEA), which, among other things, requires FDA to make nutrition labeling mandatory for almost all processed foods. FSIS' regulations, which cover meat and poultry products, largely parallel FDA's. (Meat and poultry products were not covered by NLEA.)

FDA has set May 8, 1994, as the date by which food manufacturers must comply with the new nutrition labeling regulations. FSIS requires meat and poultry processors to relabel their products by July 6, 1994. However, some newly labeled products may begin appearing in grocery stores much sooner than the deadlines.

Dietary Components

What can consumers expect? First, they will see a new name for the nutrition panel. It used to go by "Nutrition Information Per Serving." Now, it will be called "Nutrition Facts." That title will

Old Label

NUTRITION INFORMATION	PER SERVING
SERVING SIZE	5 OZ.
SERVINGS PER CONTAINER	4
CALORIES	250
PROTEIN	9g
CARBOHYDRATE	19g
FAT	11g
SODIUM	530mg

PERCENTAGE OF U.S. RECOMMENDED DAILY ALLOWANCES (U.S. RDA)	
PROTEIN	10
VITAMIN A	*
VITAMIN C	*
THIAMINE	8
RIBOFLAVIN	15
NIACIN	2
CALCIUM	20
IRON	4

*CONTAINS LESS THAN 2% OF THE U.S. RDA OF THIS NUTRIENT

Starting this year, the 'old' nutrition label format above will be replaced by the one on the right. Both labels are for a frozen macaroni and cheese product.

Key Aspects of the New Nutrition Label

A number of consumer studies conducted by FDA, as well as outside groups enabled FDA and the Food Safety and Inspection Service of the U.S. Department of Agriculture to agree on a new nutrition label. The new label is seen as offering the best opportunity to help consumers make informed food choices and to understand how a particular food fits into the total daily diet.

New heading signals a new label.

More consistent serving sizes, in both household and metric units, replace those that used to be set by manufacturers.

Nutrients required on nutrition panel are those most improtant to the health of today's consumers, most of whom need to worry about getting too much of certain items (fat, for example), rather than too few vitaminsor minerals, as in the past.

Conversion guide helps consumers learn caloric value of the energy-producing nutrients.

Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving

Calories 260 Calories from Fat 120

	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**10%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4% • Vitamin C 2%

Calcium 15% • Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodiurn	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

New mandatory component helps consumers meet dietary guidelines recommending no more than 30 percent of calories from fat.

%Daily Value shows how a food fits into the overall daily diet.

Reference values help consumers learn good diet basics. They can be adjusted, depending on a person 's calorie needs.

Types of Labels

A tabular format label (top) is allowed on packages such as this can of tuna, that have less than 40 square inches for nutrition labeling. A simplified nutrition label (bottom), in which information about some nutrients otherwise required in nutrition labeling is omitted, will appear on labels of foods, such as this can of cola, that do not contain significant amounts of certain nutrients.

Nutrition Facts

Serv. Size 1/3 cup (56g)
Servings about 3
Calories 80
Fat Cal. 10

*Percent Daily Values (DV) are based on a 2,000 calorie diet.

Amount/serving	% DV*	Amount/serving	% DV*
Total Fat 1g	2%	**Total Carb.** 0g	0%
Sat.Fat 0g	0%	Fiber 0g	0%
Cholest. 10mg	3%	Sugars 0g	
Sodium 200mg	8%	**Protein** 17g	

Vitamin A 0% • Vitamin C 0% • Calcium 0% • Iron 6%

Nutrition Facts

Serving Size 1 can (360 mL)

Amount Per Serving	
Calories 140	
	% Daily Value*
Total Fat 0g	0%
Sodium 20mg	1%
Total Carbohydrate 36g	12%
Sugars 36 g	
Protein 0g	0%

* Percent Daily Values are based on a 2,000 calorie diet.

signal to consumers that the product is newly labeled according to FDA and FSIS' new regulations.

The new panel will be built around a new set of dietary components. (See graphic, page 35.) The mandatory (underlined) and voluntary dietary components and order in which they must appear are:

- total calories
- calories from fat
- calories from saturated fat
- total fat
- saturated fat
- stearic acid (on meat and poultry products only)
- polyunsaturated fat
- monounsaturated fat
- cholesterol
- sodium
- potassium
- total carbohydrate
- dietary fiber
- soluble fiber
- insoluble fiber
- sugars
- sugar alcohol (for example, the sugar substitutes xylitol, mannitol and sorbitol)
- other carbohydrate (the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, if declared)
- protein
- vitamin A
- percent of vitamin A present as beta-carotene
- vitamin C
- calcium
- iron
- other essential vitamins and minerals.

If a food is fortified or enriched with any of the optional components, or if a claim is made about any of them, the pertinent nutrition information then becomes mandatory.

These mandatory and voluntary components are the only ones allowed on the nutrition panel. The listing of single amino acids, maltodextrin, calories from polyunsaturated fat, and calories from carbohydrate, for example, may not appear on the label.

The reason, according to Wilkening, is to help consumers focus on nutrients of public health significance. "Too much additional information could clutter the label or mislead or confuse the consumer," she said.

Nutrients required on the label, she pointed out, reflect current public health concerns and coincide with current public health recommendations. She noted that the order in which the food components and nutrients are required to appear reflects their public health significance and the order in which they were specified in NLEA.

On the new food label, the listing of thiamin, riboflavin and niacin will not be mandatory. Under the old nutrition labeling program, these vitamins were required to be listed. But because deficiencies of these are no longer a public health problem in this country, listing them is now optional.

New Format

Consumers also will see a new format, one that calls for many of the macronutrients (such as fat, cholesterol, sodium, carbohydrate, and protein) to be declared as a percent of the Daily Value—a new label reference value. The amount, in grams or milligrams per serving, of these nutrients still must be listed to their immediate right. But, for the first time, a column headed "%Daily Value" will appear.

According to Wilkening, the percent declaration of the Daily Value offers an advantage over amount declaration: The percent Daily Values put the nutrients on an equal footing in the context of a total daily diet.

For example, she said, a food is low in sodium if it has less than 140 mg of sodium. "But people look at that number, 140, and think it's a tremendous amount, when it actually is less than 6 percent of the Daily Value."

On the other hand, she said, a food with 5 g of saturated fat could be construed as being low in that nutrient just because 5 is a small number. Actually, that food would provide one-fourth the total Daily Value of 20 g of saturated fat for a 2,000-calorie diet.

"People are affected by the size of numbers," she said. "That's why percentages are helpful. They put all of the nutrients on a level playing field."

The percent Daily Value listing will carry a footnote stating that the percentages are based on a 2,000-calorie diet and that a person's individual dietary goal is based on his or her calorie needs. Some nutrition labels—at least those on larger packages—will list daily values for selected nutrients for a 2,000- and a 2,500-calorie diet and the number of calories per gram of fat, carbohydrate and protein. The calorie conversion information is required as a general guide about the caloric contributions of fat, carbohydrate and protein.

The content of micronutrients—that is, vitamins and minerals—will continue to be expressed as a percent, although the term "Daily Value" will replace "U.S. Recommended Daily Allowance."

Modifications

Some foods will carry a variation of this format. For example, the label of foods for children under 2 (except infant formula, which is exempt from nutrition labeling under NLEA) will not carry information about calories from fat, calories from saturated fat, saturated fat, polyunsaturated fat, monounsaturated fat, and cholesterol.

The reason, according to Wilkening, is to prevent parents from inadvertently assuming that infants and toddlers should restrict their fat intake, when in fact, they

should not. Fat is important during this life stage, she said, to ensure adequate growth and development.

The labels of food for children under 4 cannot include percentages of Daily Values for macronutrients, except protein, nor any footnote information, including the lists of Daily Values for selected nutrients. The reason: Other than protein, FDA has not established Daily Values for macronutrients for this age group. The percent Daily Values for vitamins and minerals is allowed, however. The content of the other nutrients must be expressed as an amount by weight in a separate column to the right of the macronutrients.

Other foods may qualify for a simplified label format. (See bottom label, page 36.) This format is allowed when the food contains insignificant amounts of seven or more of the mandatory dietary components, including total calories. "Insignificant" means that a declaration of "zero" could be made in nutrition labeling or, for total carbohydrate, dietary fiber, and protein, a declaration of "less than 1 g."

For foods for children under 2, the simplified format may be used if the product contains insignificant amounts of six or more of the following: calories, total fat, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamins A and C, calcium, and iron.

When the simplified format is used, information on total calories, total fat, total carbohydrate, protein, and sodium—even if they are present in insignificant amounts—must be listed. Calories from fat and other nutrients must be listed if they are present in more than insignificant amounts. Nutrients added to the food must be listed, too.

Serving Sizes

Whatever the format, the serving size remains the basis for reporting each nutrient's amount. However, unlike in the past, serving sizes now will be more uniform and closer to the amounts that many people actually eat. They also must be expressed in both common household and metric measures. (See accompanying table.)

Consumers will see a new name for the nutrition panel. It used to go by "Nutrition Information Per Serving." Now it will be called "Nutrition Facts."

Before, the serving size was up to the discretion of the food manufacturer. As a result, said Youngmee Park, Ph.D., a nutritionist in FDA's Office of Special Nutritionals, serving sizes often varied widely, making it difficult for consumers to compare nutritional qualities of similar products or to determine the nutrient content of the amount of food they normally ate.

The uniformity also is important, she said, for giving consistency to health claims and words describing nutrient content, such as "high fiber" and "reduced fat."

FDA and FSIS define serving size as the amount of food customarily eaten at one time. It is based on FDA- and USDA-established lists of "Reference Amounts Customarily Consumed Per Eating Occasion."

These reference amounts, which are part of the new regulations, are broken down into 139 FDA-regulated food product categories, including 11 groups of foods for children under 4, and 23 USDA meat and poultry product categories. They list the amounts of food customarily consumed per eating occasion for each food category, based primarily on national food consumption surveys. FDA's list also gives the suggested label statement for serving size declaration.

For example, the category "breads (excluding sweet quick type), rolls" has a reference amount of 50 g, and the appropriate label statement for sliced bread is "__ piece(s) __ (g)" or, for unsliced bread, "2 oz (56 g/__ inch slice)."

The serving size of products that come in discrete units, such as cookies, candy bars, and sliced products, is the number of whole units that most closely approximates the reference amount. For example, cookies have a reference amount of 30 g. The household measure closest to that amount is the number of cookies that comes closest to weighing 30 g. Thus, the serving size on the label of a cookie package in which each cookie weighs 13 g would read "2 cookies (26 g)."

If one unit weighs more than 50 percent but less than 200 percent of the reference amount, the serving size is one unit. For example, the reference amount for bread is 50 g; therefore, the label of a loaf of bread in which each slice weighs more than 25 g would state that a serving size is one slice.

For food products packaged and sold individually, if an individual package is less than 200 percent of the applicable reference amount, the item qualifies as one serving. Thus, a 360-milliliter (mL) (12 fluid-ounce) can of soda is one serving because the reference amount for carbonated beverages is 240 mL (8 fluid ounces).

However, if the product has a reference amount of 100 g or 100 mL or more and the package contains more than 150 percent but less than 200 percent of the reference amount, manufacturers have the op-

tion of deciding whether the product is one or two servings.

For example, the serving size reference amount for soup is 245 g. So a 15-ounce (420 g) can can be listed as either one or two servings.

Presentation

There also are rules governing how the nutrition information is displayed. Under existing FDA regulations, nutrition information must appear on the information panel to the immediate right of the principal panel. Thus, on boxed foods, for example, in which the principal panel is on the front of the box, the nutrition information appears on the right side of the box. Packages whose area to the immediate right is too small or not suited for such labeling may provide information on the next panel to the right.

FSIS allows nutrition information to be listed on the principal or information panels.

The new food labeling rules call for one additional variation: For packages that are 40 square inches or less, the nutrition information may be placed on any label panel.

The rules also address size and prominence of the typeface. For example, the heading "Nutrition Facts" must be set in the largest type on the nutrition panel and be highlighted in some manner, such as boldface, all capital letters, or another graphic to distinguish it from the other information. Such highlighting also is required for headings such as "Amount per serving" and "%Daily Value" and for the names of dietary components that are not subcomponents—that is, calories, total fat, cholesterol, sodium, total carbohydrate, and protein.

Exceptions and Exemptions

In some instances, special provisions exist for providing nutrition information. For example:

- Nutrition information about game meat, such as deer, bison, rabbit, quail, wild turkey, and ostrich, may be provided on counter cards, signs, or other point-of-purchase materials. Because little nutrient data exists for these foods, FDA believes that allowing this option will enable game meat producers to give first priority to collecting appropriate data and make it easier for them to update the information as it becomes available.
- FDA-regulated food packages with less than 12 square inches available for nutrition labeling do not have to carry nutrition information. However, they must provide an address or telephone number for consumers to obtain the required nutrition information.
- Packages with less than 40 square inches for nutrition labeling may present nutrition information in a tabular format (see top label, page 36), abbreviate the names of dietary components, and omit the footnotes with the list of daily values and caloric conversion information but include a footnote stating that the percent Daily Values are based on a 2,000-calorie diet or place nutrition information on other panels.

Some foods are exempt from nutrition labeling. These include:

- food produced by small businesses. (As mandated by NLEA, FDA defines a small business as one with food sales of less than $50,000 a year or total sales of less than $500,000. FSIS defines a small business as one employing 500 or fewer employees and producing no more than a certain amount of product per year.)
- food served for immediate consumption, such as that served in restaurants and hospital cafeterias, on airplanes, and by food service vendors (such as mall cookie counters, sidewalk vendors, and vending machines)
- ready-to-eat foods that are not for immediate consumption, as long as the food is primarily prepared on site—for example, many bakery, deli, and candy store items
- food shipped in bulk, as long as it is not for sale in that form to consumers
- medical foods
- plain coffee and tea, flavor extracts, food colors, some spices, and other foods that contain no significant amounts of any nutrients
- donated foods
- products intended for export
- individually wrapped FSIS-regulated products weighing less than half an ounce and making no nutrient content claims.

Although these foods are exempt, they are free to carry nutrition information, when appropriate—as long as it complies with the new regulations.

But, there will be plenty of other foods carrying the new nutrition information. Dietitian Susan Thom sees that as a plus.

"We'll all know exactly what we're putting in our mouths," she said. "So there'll be little room for excuses." ■

Paula Kurtzweil is a member of FDA's public affairs staff.

Metric Conversion Chart

Units as they will appear for serving sizes on label

Household Measure	Metric Measure
1 tsp	5 mL
1 tbsp	15 mL
1 cup	240 mL
1 fl oz	30 mL
1 oz	28 g

tsp = teaspoon
tbsp = tablespoon
fl oz = fluid ounce
oz = ounce
mL = milliliter
g = gram

TABLE 1
REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: INFANT AND TODDLER FOODS[1,2,3,4]

Product category	Reference amount	Label Statement[5]
Cereals, dry instant	15 g	___ cup (___ g)
Cereals, prepared, ready to-serve	110 g	___ cup(s) (___ g)
Other cereal and grain products, dry ready-to-eat, e.g., ready-to-eat cereals, cookies, teething biscuits, and toasts	7 g for infants and 20 g for toddlers for ready-to-eat cereals; 7 g for all others	___ cup(s) (___ g) for ready-to-eat cereals; ___ piece(s) (___ g) for others
Dinners, desserts, fruits, vegetables or soups, dry mix	15 g	___ tbsp(s) (___ g); ___ cup(s) (___ g)
Dinners, desserts, fruits, vegetables or soups, ready-to-serve, junior type	110 g	___ cup(s) (___ g); ___ cup(s) (___ mL)
Dinners, desserts, fruits, vegetables or soups, ready-to-serve, strained type	60 g	___ cup(s) (___ g); ___ cup(s) (___ mL)
Dinners, stews or soups for toddlers, ready-to-serve	170 g	___ cup(s) (___ g); ___ cup(s) (___ mL)
Fruits for toddlers, ready-to-serve	125 g	___ cup(s) (___ g)
Vegetables for toddlers, ready-to-serve	70 g	___ cup(s) (___ g)
Eggs/egg yolks, ready-to-serve	55 g	___ cup(s) (___ g)
Juices, all varieties	120 mL	4 fl oz (120 mL)

FOOTNOTES

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977-1978 and the 1987-1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, the reference amounts are for ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve, brown and serve). If not listed separately, the reference amount for the unprepared form (e.g., dry cereal) is the amount required to make the reference amount of the prepared form. Prepared means prepared for consumption (e.g., cooked).

[3] Manufactures are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).

[4] Copies of the list of products for each product category are available from the Office of Food labeling (HFS-150), center for Food safety and Applied Nutrition, Food and drug Administration, 200 C St.SW, Washington, DC 20204.

[5] The label statements are meant to provide guidance to manufacturers on the presentation of serving size information on the label, but they are not required. The term "piece" is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (e.g., sandwich for sandwiches, cookie for cookies, and bar for frozen novelties).

TABLE 2

REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY[1,2,3,4]

Product category	Reference amount	Label Statement[5]
BAKERY PRODUCTS:		
Biscuits, croissants, bagels, tortillas, soft bread sticks, soft pretzels, corn bread, hush puppies	55 g	___ piece(s) (___ g)
Breads (excluding sweet quick type), rolls	50 g	___ piece(s) (___ g) for sliced bread and distinct pieces (e.g., rolls); 2 oz (56 g/___ inch slice) for unsliced bread
Bread sticks—see crackers		
Toaster pastries—see coffee cakes		
Brownies	40 g	___ piece(s) (___ g) for distinct pieces; fractional slice (___ g) for bulk
Cakes, heavy weight (cheese cake; pineapple upside-down cake; fruit, nut, and vegetable cakes with more than or equal to 35 percent of the finished weight as fruit, nuts, or vegetables or any of these combined)[6]	125 g	___ piece(s) (___ g) for distinct pieces (e.g. sliced or individually packaged products); fractional slice (___ g) for large discrete units
Cakes, medium weight (chemically leavened cake with or without icing or filling except those classified as light weight cake; fruit, nut, and vegetable cake with less than 35 percent of the finished weight as fruit, nuts, or vegetables or any of these combined; light weight cake with icing: Boston cream pie; cupcake; eclair; cream puff)[7]	80 g	___ piece(s) (___ g) for distinct pieces (e.g. cupcakes); ___ fractional slice (___ g) for large discrete units
Cakes, light weight (angel food, chiffon, or sponge cake without icing or filling)	55 g	___ piece(s) (___ g) for distinct pieces (e.g. sliced or individually packaged products); ___ fractional slice (___ g) for large discrete units
Coffee cakes, crumb cakes, doughnuts, Danish, sweet rolls, sweet quick type breads, muffins, toaster pastries	55 g	___ piece(s) (___ g) for sliced bread and distinct pieces (e.g. doughnut); 2 oz (56 g/visual unit of measure) for bulk products (e.g., unsliced bread)
Cookies	30 g	___ piece(s) (___ g)
Crackers that are usually not used as snack, melba toast, hard bread sticks, ice cream cones[8]	15 g	___ piece(s) (___ g)
Crackers that are usually used as snacks	30 g	___ piece(s) (___ g)
Croutons	7 g	___ tbsp(s) (___ g); ___ cup(s) (___ g); ___ piece(s) (___ g) for large pieces
French toast, pancakes, variety mixes	110 g prepared for french toast and pancakes; 40 g dry mix for variety mixes	___ piece(s) (___ g); ___ cup(s) (___ g) for dry mix
Grain-based bars with or without filling or coating, e.g., breakfast bars, granola bars, rice cereal bars	40 g	___ piece(s) (___ g)
Ice cream cones--see crackers		

TABLE 2--Continued

REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY [1,2,3,4]

Product category	Reference amount	Label Statement[5]
BAKERY PRODUCTS: (continued)		
Pies, cobblers, fruit crisps, turnovers, other pastries	125 g	___ piece(s) (___ g) for distinct pieces; ___ fractional slice (___ g) for large discrete units
Pie crust	1/6 of 8 inch crust; 1/3 of 9 inch crust	1/6 of 8 inch crust (___ g); 1/8 of 9 inch crust (___ g)
Pizza crust	55 g	fractional slice (___ g)
Taco shells, hard	30 g	___ shell(s) (___ g)
Waffles	85 g	___ Piece(s) (___ g)
BEVERAGES:		
Carbonated and noncarbonated beverages, wine coolers, water	240 mL	8 fl oz (240 mL)
Coffee or tea, flavored and sweetened	240 mL prepared	8 fl oz (240 mL)
CEREALS AND OTHER GRAIN PRODUCTS:		
Breakfast cereals (hot cereal type), hominy grits	1 cup prepared, 40 g plain dry cereal, 55 g flavored; sweetened dry cereal.	___ cup(s) (___ g)
Breakfast cereals, ready-to-eat, weighing less than 20 g per cup, e.g., plain puffed cereal grains	15 g	___ cup(s) (___ g)
Breakfast cereals, ready-to-eat weighing 20 g or more but less than 43 g per cup; high fiber cereals containing 28 g or more of fiber per 100 g	30 g	___ cup(s) (___ g)
Breakfast cereals. ready-to-eat, weighing 43 g or more per cup; biscuit types.	55 g	___ piece(s) (___ g) for large distinct pieces (e.g., biscuit type); ___ cup(s) (___ g) for all others
Bran or wheat germ	15 g	___ tbsp(s) (___ g); ___ cup(s) (___ g)
Flours or cornmeal	30 g	___ tbsp(s) (___ g); ___ cup(s) (___ g)
Grains, e.g., rice, barley, plain	140 g prepared; 45 g dry	___ cup(s) (___ g)
Pastas, plain	140 g prepared; 55 g dry	___ cup(s) (___ g); ___ piece(s) (___ g) for large pieces (e.g. large shells or lasagna noodles) or 2 oz (56 g/visual unit of measure) for dry bulk products (e.g., spaghetti)
Pastas, dry, ready-to-eat, fried canned chow mein noodles	25 g	___ cup(s) (___ g)
Starches, e.g., cornstarch, potato starch, tapioca.	10 g	___ tbsp (___ g)
Stuffing	100 g	___ cup(s) (___ g)
DAIRY PRODUCTS AND SUBSTITUTES:		
Cheese, cottage	110 g	___ cup(s) (___ g)
Cheese used primarily as ingredients, e.g., dry cottage cheese, ricotta cheese.	55 g	___ cup(s) (___ g)
Cheese, grated hard, e.g., Parmesan, Romano	5 g	___ tbsp (___ g)

DAIRY PRODUCTS AND SUBSTITUTES: (cont.)		
Cheese, all others except those listed as separate categories—includes cream cheese and cheese spread.	30 g	___ piece(s) (___ g) for distinct pieces; ___ tbsp(s) (___ g) for cream cheese and cheese spread; 1 oz (28 g/visual unit of measure) for bulk
Cheese sauce—see sauce category		
Cream or cream substitutes, fluid	15 mL	1 tbsp (15 mL)
Cream or cream substitutes, powder	2 g	___ tsp (___ g)
Cream, half & half	30 mL	2 tbsp (30 mL)
Eggnog	120 mL	1/2 cup (120 mL); 4 fl oz (120 mL)
Milk, condensed, undiluted	30 mL	2 tbsp (30 mL)
Milk, evaporated, undiluted	30 mL	2 tbsp (30 mL)
Milk, milk-based drinks, e.g., instant breakfast, meal replacement, cocoa.	240 mL	1 cup (240 mL); 8 fl oz (240 mL)
Shakes or shake substitutes, e.g., dairy shake mixes, fruit frost mixes	240 mL	1 cup (240 mL); 8 fl oz (240 mL)
Sour cream	30 g	___ tbsp (___ g)
Yogurt	225 g	___ cup(s) (___ g)
DESSERTS:		
Ice cream, ice milk, frozen yogurt, sherbet: all types, bulk and novelties (e.g., bars, sandwiches, cones)	1/2 cup-includes the volume for coatings and wafers for the novelty type varieties.	___ piece(s) (___ g) for individually wrapped or packaged products; 1/2 cup (___ g) for others
Frozen flavored and sweetened ice and pops, frozen fruit juices: all types, bulk and novelties (e.g., bars, cups).	85 g	___ piece(s) (___ g) for individually wrapped or packaged products; ___ cup(s) (___ g) for others
Sundae	1 cup	1 cup (___ g)
Custards, gelatin or pudding	1/2 cup	___ piece(s) (___ g) for distinct unit (e.g. individually packaged products); 1/2 cup (___ g) for bulk
DESSERT TOPPINGS AND FILLINGS:		
Cake frostings or icings	35 g	___ tbsp(s) (___ g)
Other dessert toppings, e.g., fruits, syrups, spreads, marshmallow cream, nuts, dairy and nondairy whipped toppings	2 tbsp	2 tbsp (___ g; 2 tbsp (30 mL)
Pie filling	85 g	___ cups(s) (___ g)
EGG AND EGG SUBSTITUTES:		
Egg mixtures e.g., egg foo young, scrambled eggs, omelets	110 g	___ piece(s) (___ g) for discrete pieces; ___ cup(s) (___ g)
Eggs (all sizes)	50 g	1 large, medium, etc. (___ g)
Egg substitutes	An amount to make 1 large (50 g) egg	___ cup(s) (___ g); ___ cup(s) (___ mL)
FATS AND OILS:		
Butter, margarine, oil, shortening	1 tbsp	1 tbsp (___ g); 1 tbsp (15 mL)
Butter replacement, powder	2 g	___ tbsp(s) (___ g)
Dressings for salads	30 g	___ tbsp (___ g); ___ tbsp (___ mL)
Mayonnaise, sandwich spreads, mayonnaise-type dressings	15 g	___ tbsp (___ g)
Spray types	0.25 g	About ___ seconds spray (___ g)

FISH, SHELLFISH, GAME MEATS[10], AND MEAT OR POULTRY SUBSTITUTES:		
Bacon substitutes, canned anchovies, anchovy pastes, caviar	15 g	___ piece(s) (___ g) for discrete pieces; ___ tbsp(s) (___ g) for others
Dried, e.g., jerky	30 g	___ piece(s) (___ g)
Entrees with sauce, e.g., fish with cream sauce, shrimp with lobster sauce	140 g cooked	___ cup(s) (___ g); 5 oz (140 g/visual unit of measure) if not measurable by cup
Entrees without sauce, e.g., plain or fried fish and shellfish, fish and shellfish cake	85 g cooked; 110 g uncooked[12]	___ piece(s) (___ g) for discrete pieces; ___ cup(s) (___ g); ___ oz (___ g/visual unit of measure) if not measurable by cup[13]
Fish, shellfish or game meal[10], canned[11]	55 g	___ piece(s) (___ g) for discrete pieces; ___ cup(s) (___ g); 2 oz (56 g/___ cup) for products that are difficult to measure the g weight of cup measure (e.g. tuna); 2 oz (56 g/___ pieces) for products that naturally vary in size (e.g., sardines)
Substitute for luncheon meat, meat spreads, Canadian bacon, sausages and frankfurters	55 g	___ piece(s) (___ g) for distinct pieces (e.g., slices, links); ___ cup(s) (___ g); 2 oz (56 g/visual unit of measure) for nondiscrete bulk product
Smoked or pickled fish, shellfish, or game meat[10]; fish or shellfish spread	55 g	___ piece(s) (___ g) for distinct pieces (e.g., slices, links) or ___ cup(s) (___ g); 2 oz (56 g/visual unit of measure) for nondiscrete bulk product
Substitutes for bacon bits—see miscellaneous category		
FRUITS AND FRUIT JUICES:		
Candied or pickled[11]	30 g	___ piece(s) (___ g)
Dehydrated fruits—see snacks category		
Dried	40 g	___ piece(s) (___ g) for large pieces (e.g., dates, figs, prunes); ___ cup(s) (___ g) for small pieces (e.g., raisins)
Fruits for garnish or flavor, e.g., maraschino cherries[11]	4 g	1 cherry (___ g)
Fruit relishes, eg, cranberry sauce, cranberry relish	70 g	___ cup(s) (___ g)
Fruits used primarily as ingredients, avocado	30 g	See footnote 13
Fruits used primarily as ingredients, others (cranberries, lemon, lime)	55 g	___ piece(s) (___ g) for large fruits; ___ cup(s) (___ g) for small fruits measurable by cup[13]
Watermelon	280 g	See footnote 13
All other fruits (except those listed as separate categories), fresh, canned, or frozen	140 g	___ piece(s) (___ g) for large pieces (e.g., strawberries, prunes, apricots, etc.); ___ cup(s) (___ g) for small pieces (e.g., blueberries, raspberries, etc.)[13]
Juices, nectars, fruit drinks	240 mL	8 fl oz (240 mL)
Juices used as ingredients, e.g., lemon juice, lime juice	5 mL	1 tsp (5 mL)

LEGUMES:		
Bean cake (tofu)[11], tempeh	85 g	___ piece(s) (___ g) for discrete pieces; 3 oz (84 g/visual unit of measure) for bulk products
Beans, plain or in sauce	130 g for beans in sauce or canned in liquid and refried beans prepared; 90 g for others prepared; 35 g dry.	___ cup (___ g)
MISCELLANEOUS CATEGORY:		
Baking powder, baking soda, pectin	1 g	___ tsp (___ g)
Baking decorations, e.g., colored sugars and sprinkles for cookies, cake decorations	1 tsp or 4 g if not measurable by teaspoon	___ piece(s) (___ g) for discrete pieces; 1 tsp (___ g)
Batter mixes, bread crumbs	30 g	___ tbsp(s) (___ g); ___ cup(s) (___ g)
Cooking wine	30 mL	2 tbsp (30 mL)
Dietary supplements not in conventional food form	The maximum amount recommended, as appropriate, on the label for consumption per eating occasion or, in the absence of recommendations, 1 unit, e.g., tablet, capsule, packet, teaspoonful, etc.	___ tablet(s), ___ capsule(s), ___ packet(s), ___ tsp(s) (___ g), etc.
Drink mixers (without alcohol)	Amount to make 240 mL drink (without ice)	___ fl oz (___ mL)
Chewing gum[9]	3 g	___ piece(s) (___ g)
Meat, poultry and fish coating mixes, dry; seasoning mixes, dry e.g., chili seasoning mixes, pasta salad seasoning mixes	Amount to make one reference amount of final dish	___ tsps (___ g); ___ tbsp(s) (___ g)
Salad and potato toppers, e.g., salad crunchies, salad crispins, substitutes for bacon bits	7 g	___ tbsp(s) (___ g)
Salt, salt substitutes, seasoning salts (e.g., garlic salt)	1 g	___ tsps (___ g); ___ piece(s) (___ g) for discrete pieces (e.g., individually packaged products)
Spices, herbs (other than dietary supplements)	1/4 tsp or 0.5 g if not measurable by teaspoon	1/4 tsp (___ g); ___ piece(s) (___ g) if not measurable by teaspoons (e.g., bay leaf)
MIXED DISHES:		
Measurable with cup, e.g., casseroles, hash, macaroni and cheese, pot pies, spaghetti with sauce, stews, etc.	1 cup	1 cup (___ g)
Not measurable with cup, e.g., burritos egg rolls, enchiladas, pizza, pizza rolls, quiche, all types of sandwiches	140 g, add 55 g for products with gravy or sauce topping, e.g., enchilada with cheese sauce, crepe with white sauce[14]	___ piece(s) (___ g) for discrete pieces; ___ fractional slice (___ g) for large discrete units
NUTS AND SEEDS:		
Nuts, seeds, and mixtures, all types: sliced, chopped, slivered, and whole	30 g	___ piece(s) (___ f) for large pieces (e.g., unshelled nuts); ___ tbsp(s) (___ g); cup(s) (___ g) for small pieces (e.g., peanuts, sunflower seeds)
Nut and seed butters, pastes, or creams	2 tbsp	2 tbsp (___ g)
Coconut, nut and seed flours	15 g	___ Tbsp(s) (___ g); ___ cup (___ g)

POTATOES AND SWEET POTATOES/YAMS:		
French fries, hash browns, skins, or pancakes	70 g prepared; 85 g for frozen unprepared french fries	___ piece(s) (___ g) for large distinct pieces (e.g., patties, skins); 2.5 oz (70 g/___ pieces) for prepared fries; 3 oz (84 g/___ pieces) for unprepared fries
Mashed, candied, stuffed, or with sauce	140 g	___ piece(s) (___ g) for discrete pieces (e.g., stuffed potato); ___ cup(s) (___ g)
Plain, fresh, canned, or frozen	110 g for fresh or frozen; 125 g for vacuum packed; 160 g for canned in liquid	___ piece(s) (___ g), for discrete pieces; ___ cup(s) (___ g) for sliced or chopped products
SALADS:		
Gelatin salad	120 g	___ cup (___ g)
Pasta or potato salad	140 g	___ cup(s) (___ g)
All other salads, e.g., egg, fish, shellfish, bean, fruit, or vegetable salads	100 g	___ cup(s) (___ g)
SAUCES, DIPS, GRAVIES AND CONDIMENTS:		
Barbecue sauce, hollandaise sauce, tartar sauce, other sauces for dipping (e.g., mustard sauce, sweet and sour sauce), all dips (e.g., bean dips, dairy-based dips, salsa)	2 tbsp	2 tbsp (___ g); 2 tbsp (30 mL)
Major main entree sauces, e.g., spaghetti sauce	125 g	___ cup (___ g); ___ cup (___ mL)
Minor main entree sauces (e.g., pizza sauce, pesto sauce), other sauces used as toppings (e.g., gravy, white sauce, cheese sauce), cocktail sauce	1/4 cup	1/4 cup (___ g); 1/4 cup (60 mL)
Major condiments, e.g., catsup, steak sauce, soy sauce, vinegar, teriyaki sauce, marinades	1 tbsp	1 tbsp (___ g); 1 tbsp (15 mL)
Minor condiments, e.g., horseradish, hot sauces, mustards, worcestershire sauce	1 tsp	1 tsp (___ g); 1 tsp (5 mL)
SNACKS:		
All varieties, chips, pretzels, popcorns, extruded snacks, fruit-based snacks (e.g., fruit chips,) grain-based snack mixes	30 g	___ cup(s) (___ g) for small pieces (e.g., popcorn); ___ piece(s) (___ g) for large pieces (e.g., large pretzels; pressed dried fruit sheet); 1 oz (28 g/visual unit of measure) for bulk products (e.g., potato chips)
SOUPS:		
All varieties	245 g	___ cup (___ g); ___ cup (___ mL)
SUGARS AND SWEETS:		
Baking candies (e.g., chips)	15 g	___ piece(s) (___ g) for large pieces; ___ tbsp(s) (___ g) for small pieces; 1/2 oz (14 g/visual unit of measure) for bulk products
Hard candies, breath mints	2 g	___ piece(s) (___ g)
Hard candies, roll-type, mini-size In dispenser packages	5 g	___ piece(s) (___ g)
Hard candies, others	15 g	___ piece(s) (___ g) for large pieces; ___ tbsp(s) (___ g) for "mini-size" candies measurable by tablespoon; 1/2 oz (14 g/visual unit of measure) for bulk products

All other candies	40 g	___ piece(s) (___ g); 1 1/2 oz (42 g/visual unit of measure) for bulk products
Confectioner's sugar	30 g	___ cup (___ g)
Honey, jams, jellies, butter, molasses	1 tbsp	1 tbsp (___); 1 tbsp (15 mL)
Marshmallows	30 g	___ cup(s) (___ g) for small pieces; ___ piece(s) (___ g) for large pieces
Sugar	4 g	___ tsp (___ g); ___ piece(s) (___ g) for discrete pieces (e.g., sugar cubes, individually packaged products)
SUGARS AND SWEETS:		
Sugar substitutes	An amount equivalent to one reference amount for sugar in sweetness	___ tsp(s) (___ g) for solids; ___ drop(s) (___ g) for liquid; ___ pieces(s) (___) (e.g., individually packaged products)
Syrups	30 mL for syrups used primarily as an ingredient (e.g., light or dark corn syrup); 60 mL for all others	2 tbsp (30 mL) for syrups used primarily as an ingredient; 1/4 cup (60 mL) for all others
VEGETABLES:		
Vegetables primarily used for garnish or flavor, e.g., pimento, parsley	4 g	___ piece(s) (___ g); ___ tbsp(s) (___ g) for chopped products
Chili pepper, green onion	30 g	___ piece(s) (___ g)[13]; ___ tbsp(s) (___ g); ___ cup(s) (___ g) for sliced or chopped products
All other vegetables without sauce: fresh, canned, or frozen	85 g for fresh or frozen; 95 g for vacuum packed; 130 g for canned in liquid, cream-style corn, canned or stewed tomatoes, pumpkin, or winter squash.	___ piece(s) (___ g) for large pieces (e.g., brussels sprouts); ___ cup(s) (___ g) for small pieces (e.g., cut corn, green peas); 3 oz (84 g/visual unit of measure) if not measurable by cup[13]
All other vegetables with sauce: fresh, canned, or frozen	110 g	___ piece(s) (___ g) for large pieces (e.g., brussels sprouts); ___ cup(s) (___ g) for small pieces (e.g., cut corn, green peas); 4 oz (112 g/visual unit of measure) if not measurable by cup
Vegetable juice	240 mL	8 fl oz (240 mL)
Olives[11]	15 g	___ piece(s) (___ g); ___ tbsp(s) (___ g) for sliced products
Pickles, all types	30g	1 oz (28 g/visual unit of measure)
Pickle relishes	15 g	___ tbsp (___ g)
Vegetable pastes, e.g., tomato paste	30 g	___ tbsp (___ g)
Vegetable sauces or purees, e.g, tomato sauce, tomato puree	60 g	___ cup (___ g); ___ cup (___ mL)

FOOTNOTES

[1] These values represent the amount (edible portion) of food customarily consumed per eating occasion and were primarily derived from the 1977-1978 and the 1977-1978 and the 1987-1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve, brown and serve). If not listed separately, the reference amount for the unprepared form (e.g., dry mixes; concentrates; dough; batter; dry, fresh, and frozen pasta) is the amount required to make the reference amount of the prepared form. Prepared means prepared for consumption (e.g., cooked).

[3] Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).

[4] Copies of the list of products for each product category are available from the Office of Food Labeling (HFS09150), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

[5] The label statements are meant to provide guidance to manufacturers on the presentation of serving size information on the label, but they are not required. The term "piece" is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (e.g., sandwich for sandwiches, cookie for cookies, and bar for ice cream bars). The guidance provided is for the label statement of products in ready-to-serve or almost ready-to-serve form. The guidance does not apply to the products which require further preparation for consumption (e.g., dry mixes, concentrates) unless specifically stated in the product category, reference amount, or label statement column that it is for these forms of the product. For products that require further preparation, manufacturers must determine the label statement following the rules in §101.9(b) using the reference amount determined according to §101.12(c).

[6] Includes cake that weigh 10 g or more per cubic inch.

[7] Includes cakes that weigh 4 g or more per cubic inch but less than 10 g per cubic inch.

[8] Includes cake that weigh less than 4 g per cubic inch.

[9] Label serving size for ice cream cones and eggs of all sizes will be 1 unit. Label serving size of all chewing gums that weigh more than the reference amount that can reasonably be consumed at a single-eating occasion will be 1 unit.

[10] Animal products not covered under the Federal meat inspection Act or the Poultry Products Act, such as flesh products from deer, bison, rabbit, quail, wild turkey, geese, ostrich, etc.

[11] If packed or canned in liquid, the reference amount is for the drained solids, except for products in which both the solids and liquids are customarily consumed (e.g., canned chopped clam in juice)

[12] The reference amount for the uncooked form does not apply to raw fish in §101.45 or to single-ingredient products that consist of fish or game meat as provided for in §101.9(j)(11)

[13] For raw fruit, vegetables and fish, manufactures should follow the label statement for the serving size specified in Appendices A and B to the regulation entitled "Food Labeling: guidelines for Voluntary Nutrition Labeling; and Identification of the 20 Most Frequently Consumed Raw Fruits, Vegetables and Fish; definition of Substantial compliance; Correction" (56 FR 60880 as amended 57 FR 8174, March 6, 1992).

[14] Pizza sauce is part of the pizza and is not considered to be a sauce topping.

Rounding Rules for Serving Size Regulation

MEASUREMENT TYPE	UNIT	INCREMENT ROUNDING
Discrete Units	Servings	≤ 50% of the Reference Amount (RA): number of units closest to the RA = 1 serving > 50% to < 67% of RA: then, 1 unit = 1 serving OR 2 units = 1 serving ≥ 67% to < 200% of RA: then, 1 unit = 1 serving ≥ 200% of RA: then, 1 unit = 1 serving, if it can reasonably be consumed at a single eating occasion
Common Household Measures	Volume: Cup (cup) Tablespoon (Tbsp) Teaspoon (tsp) Fluid Ounce (fl oz) Weight: Ounce (oz)	Use "cup" in 1/3 or 1/4 cup increments, except may use "fl oz" for beverages ≥ 2 Tbsp & < 1/4 cup = whole Tbsp Between 1 & 2 Tbsp, may use the increments of: 1, 1 1/3, 1 1/2, 1 2/3, 2 ≥ 1 tsp & < 1 Tbsp = whole tsp < 1 tsp = 1/4 tsp increments Ounce (oz) measures = 0.5 oz increments Fluid ounce (fl oz) = whole number increments Serving sizes that fall half-way between two serving sizes, manufacturers shall round up to the next incremental size.
Metric Measures	Volume: Milliliters (ml) Weight: Grem (g) Milligrem (mg)	> 5 = nearest whole number ≥ 2 and < 5 = nearest 0.5 < 2 = nearest 0.1
Number of Servings/ Container	Numbers	Round to the nearest whole number except for servings between 2 and 5 servings. Between 2 and 5 servings = nearest 0.5 serving Roundings should be indicated by the term "about"

Rounding Rules for Declering Nutriente

per Technical amendments of mandatory nutrition labeling final rule, August, 1993

Nutrient /Serving	(M) or (V)*	Core Nutrient	Units	Increment Rounding **	Insignificant Amount	Other Relevent Information ***
Calories	M	X	cal	< 5 cal — express as zero ≤ 50 cal — express to nearest 5 cal increment > 50 cal — express to nearest 10 cal increment	< 5 cal	§ 101.9(c)(1)
Calories from fat	M		cal	< 5 cal — express as zero ≤ 50 cal — express to nearest 5 cal increment > 50 cal — express to nearest 10 cal increment	< 5 cal	If < 0.5 g fat: "*cal from fat*" not required § 101.9(c)(1)(ii)
Calories from saturated fat	V		cal	< 5 cal — express as zero ≤ 50 cal — express to nearest 5 cal increment > 50 cal — express to nearest 10 cal increment	< 5 cal	§ 101.9(c)(1)(iii)
Total fat	M	X	g	< 0.5 g — express as zero < 5 g — express to nearest 0.5 g increment ≥ 5 g — express to nearest 1 g increment	< 0.5 g	§ 101.9(c)(2)
Saturated fat	M		g	< 0.5 g — express as zero < 5 g — express to nearest 0.5 g increment ≥ 5 g — express to nearest 1 g increment	< 0.5 g	§ 101.9(c)(2)(i)
Polyunsaturated & Monounsaturated fat	V		g	< 0.5 g — express as zero < 5 g — express to nearest 0.5 g increment ≥ 5 g — express to nearest 1 g increment	< 0.5 g	§ 101.9(c)(2)(ii) & iiii)
Cholesterol	M		mg	< 2 mg — express as zero 2 - 5 mg — express as "less then 5 mg" > 5 mg — express to nearest 5 mg increment	< 2 mg	§ 101.9(c)(3)
Sodium	M	X	mg	< 5 mg — express as zero 5 - 140 mg — express to nearest 5 mg increment > 140 mg — express to nearest 10 mg increment	< 5 mg	§ 101.9(c)(4)
Potessium	V		mg	< 5 mg — express as zero 5 - 140 mg — express to nearest 5 mg increment > 140 mg — express to nearest 10 mg increment	< 5 mg	§ 101.9(c)(5)
Totel cerbohydrate	M	X	g	< 0.5 g — express as zero < 1 g — express as "Contains less then 1 g" OR "less then 1 g" ≥ 1 g — express to nearest 1 g increment	< 1 g	§ 101.9(c)(6)
Dietary fiber	M		g	< 0.5 g — express as zero < 1 g — express as "Contains less then 1 g" OR "less then 1 g" ≥ 1 g — express to nearest 1 g increment	< 1 g	§ 101.9(c)(6)(i)

Rounding Rules for Declering Nutrients

per Technical amendmente of mandatory nutrition labeling final rule, August, 1993

Nutrient /Serving	(M) or (V)*	Core Nutrient	Units	Increment Rounding **	Insignificent Amount	Other Relevent Information ***
Soluble & Insoluble fiber	V		g	< 0.5 g — express as zero < 1 g — express as "Contains less then 1 g" OR "less then 1 g" ≥ 1 g — express to nearest 1 g increment	< 0.5 g	§ 101.9(c)(6)(i)(A) & (B)
Sugars	M		g	< 0.5 g — express as zero < 1 g — express as "Contains less then 1 g" OR "less then 1 g" ≥ 1 g — express to nearest 1 g increment	< 0.5 g	§ 101.9(c)(6)(ii)
Suger alcohol	V		g	< 0.5 g — express as zero < 1 g — express as "Contains less then 1 g" OR "less then 1 g" ≥ 1 g — express to nearest 1 g increment	< 0.5 g	§ 101.9(c)(6)(iii)
Other carbohydrate	V		g	< 0.5 g — express as zero < 1 g — express as "Contains less then 1 g" OR "less then 1 g" ≥ 1 g — express to nearest 1 g increment	< 0.5 g	§ 101.9(c)(6)(iv)
Protein	M	X	g	< 0.5 g — express as zero < 1 g — express as "Contains less then 1 g" OR "less then 1 g" ≥ 1 g — express to nearest 1 g increment	< 1 g	§ 101.9(c)(7)
Vitamins & minerals	M		% DV	< 2% of RDI — may be expressed as: (1) 2% if actual amount is 1.0% or more (2) zero (3) an asterisk that refers to statement "Contains less then 2% of the Daily Value of this (these) nutrient (nutrients)" (4) for Vit A, C, calcium, iron: statement "Not a significant source of ____ (listing the vitamins or minerals omitted)" ≤ 10% of RDI — express to nearest 2% increment >10% - ≤ 50% of RDI — express to nearest 5% increment > 50% of RDI — express to nearest 10% increment	< 2% RDI	Vitamins and minerals other then vit A, C, calcium and iron, listed in (8)(iv), are mandatory if added as nutrient supplement in food or if claim is made § 101.9(c)(8)(iii) & (iv)
Beta-carotene	V		% Vit A	≤ 10% of Vit. A — express to nearest 2% increment >10% - ≤ 50% of Vit A — express to nearest 5% increment > 50% of Vit A — express to nearest 10% increment		§ 101 9(c)(8)(vi)

* (M) = Mandatory and (V) = Voluntary

** To express to the nearest 1 g increment, amounts exactly halfway between two whole number or higher (e.g., 2.50 to 2.99 g) round up (e.g., 3 g), and amounts less then halfway between two whole numbers (e.g., 2.01 to 2.49 g) round down (e.g., 2 g).

*** NOTES FOR ROUNDING % Daily Value (DV):

(1) To calculate %DV, divide either the actual (unrounded) quantitative amount or the declared (rounded) amount by the appropriate RDI or DRV. Use whichever amount will provide the greatest consistency on the food label and prevent unnecessary consumer confusion (§ 101.9(d)(7)(ii)).

(2) When %DV values fall between two whole numbers, rounding shall be as follows:
- for values exactly halfway between two whole numbers or higher (e.g., 2.50 to 2.99) the values shall round up (e.g., 3%).
- for values less then halfway between two whole numbers (e.g., 2.01 to 2.49) the values shall round down (e.g. 2%).

(March 7, 1994)